

EPA Registration No.
352-903
Vol. 1

MATERIAL TO BE ADDED TO JACKET

REG #: 11654-23

Description: Refine & Oil of Nephth Catana 15% (Whod

if applicable, check all that are attached:		Send to CSC
<input type="checkbox"/>	new stamped accepted label	
<input type="checkbox"/>	new CSF	
<input type="checkbox"/>	notification	
<input checked="" type="checkbox"/>	other: <u>Un Acceptable Storage Stability</u> <u>Corrosion Characteristic Study</u>	

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

SEP 01 2010

Reviewer: Menyon Adams Date: _____

Phone: (703) 347-8496 Division: BPPD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 01 2010

Thomas C. McEntee
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 1988-0402

Subject: Refined Oil of Nepeta Cataria 15% Lotion
EPA Registration No. 71654-23
Storage Stability and Corrosion Characteristics
Decision # 434659
Application Dated: May 21, 2010

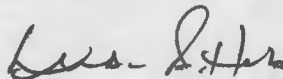
Dear Mr. McEntee:

The Storage Stability and Corrosion Characteristics Guideline study (OPPTS 830.6317 and OPPTS 830.6320) referred to above submitted in response to the terms and conditions of registration as issued July 29, 2009 is **unacceptable but upgradeable**. The following need to be addressed:

1. You must clearly demonstrate the stability of the two active ingredients listed on your Confidential Statement of Formula (CSF) by showing whether or not the nominal concentration of these two ingredients are within the certified limits listed on the CSF after 12 months of storage.
2. You must explain the percentage values that are below the lower certified limits for the active ingredients.
3. You must justify why sampling was not performed from each container type at each time interval.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at:
adams.menyon@epa.gov.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

SYMBOL	▶ 7511P							
USERNAME	▶ Adams							
DATE	▶ 09/01/10							



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: August 25, 2010

SUBJECT: Science Review of Storage Stability and Corrosion Characteristics Studies for Several Products Containing Oil of *Nepeta Cataria* as their Active Ingredient: Refined Oil of *Nepeta cataria* Technical; Refined Oil of *Nepeta cataria* 7% Lotion; Refined Oil of *Nepeta cataria* 15% Lotion; Refined Oil of *Nepeta cataria* 7% Liquid; Refined Oil of *Nepeta cataria* 15% Liquid

EPA File Symbol Numbers: 71654-20; 71654-21; 71654-23; 71654-24; 71654-25
Decision Numbers: 434656; 434657; 434659; 434660; 434661
DP Barcode: 378691; 378694; 378693; 378696; 378695
PC Code: 004801
CAS Number: 8023-84-5
MRID Number: 48106201

FROM: Gina M. Casciano, M.S., Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

E. I. du Pont de Nemours and Company requests the review of a recently completed Storage Stability and Corrosion Characteristics study that includes five products containing *Nepeta cataria* oils as their active ingredient (MRID 48106201). Each product was granted a Conditional Section 3(c) Registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) between December 4, 2008, and March 26, 2009.

RECOMMENDATIONS AND CONCLUSIONS

1. Storage stability data presented appear to indicate that the test substance was stable for 1 year with minimum change in active ingredient concentration and no change in appearance. However, the registrant did not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their Confidential Statement of Formula (CSF). The storage stability analysis is **UNACCEPTABLE**, but upgradable. The registrant must:
 - a. Demonstrate the stability of each of the two ingredients that are listed as active ingredients on the Confidential Statement of Formula (CSF). Specifically, the registrant must show whether or not the nominal concentrations of these two ingredients remain above the lowest respective certified limit after 12 months of storage.
 - b. Explain those values lying outside the active ingredient certified limits for each product.
 - c. Justify why sampling for each container type was not performed at each time interval.
2. The Corrosion Characteristics analysis indicates that the test substance is not corrosive to packaging materials. The corrosion characteristics data are **ACCEPTABLE**; no additional data are required.

STUDY SUMMARIES

Storage Stability

The registrant has submitted MRID 48106201 to fulfill the Storage Stability data requirement for the manufacturing-use product (MP) Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20), and end-use products (EPs) Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21), Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23), Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24), and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25). The study was conducted in accordance with OPPTS Guideline 830.6317 with the following deviations:

- Samples of each product were contained in glass and high density polyethylene (HDPE). Samples of the TGAI/MP were also contained in aluminum (Al). Not all container types were sampled at each time point during the study (0 months, 3 months, 6 months, etc).
- No sample reading were taken at 9 or 12 months. In lieu of a 12-month reading, the samples were read at T = 15 months.

All samples were stored at 25°C and 50% relative humidity for the duration of the study (June, 2001-October, 2008). For each analysis, three portions of the sample to be analyzed were weighted, mixed with a solution of the internal standard 1,2-dibromobenzene and analyzed via

gas chromatograph. (Standards used for calibration/comparison included nepetalactones, dihydronepetalactones, nepetalic acids, pulegic acids, and beta-caryophyllene.) Each of the triplicate samples was analyzed twice in a back to back fashion, thus giving six readings per sampling event. The six values are averaged and these results are displayed in Tables 1-5, below. Because the chromatography can be different for a sample when analyzed as prepared compared to the chromatography of the sample when diluted (sometimes the more concentrated peak will "tail" extensively and can cause the peak not to be within the desired window), all samples were analyzed as prepared, and also analyzed after dilution. The registrant states in their report (MRID 48106201) that the data for the "neat" or "as prepared" samples are reported for reference only, and should not be used in analysis due to the tailing of such peaks and the potentially erroneous GC readings they produce. Therefore, only the results from the diluted preparations are analyzed here.

BPPD has calculated the percent change in active ingredient for each sample. Samples were compared to T = 0 values, unless an analysis was not done at T = 0. Then, the percent change was calculated from the earliest recorded value. **The registrant must justify why sampling did not take place from each container type at each time interval.**

Table 1: Results for Refined Oil of *Nepeta cataria* Technical (EPA Reg No. 71654-20)[†]

	Glass		HDPE		Aluminum	
	% AI	% change	% AI	% change	% AI	% change
T = 0	96.28	n/a	n/d	n/a	n/d	n/a
T = 3 mo	n/d	n/a	85.07	n/a	83.93	n/a
T = 6 mo	92.63	-3.79	93.32	9.70	92.46	10.16
T = 15 mo	91.14	-5.34	93.95	10.44	93.13	10.96

Table 2: Results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21)[†]

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.38	n/a	n/d	n/a
T = 3 mo	n/d	n/a	5.89	n/a
T = 6 mo	n/d	n/a	6.81	15.6
T = 15 mo	6.13	-3.92	6.08	3.23

Table 3: Results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23)[†]

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.86	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.17	n/a
T = 6 mo	n/d	n/a	15.48	17.54
T = 15 mo	14.07	-5.32	14.41	9.42

Table 4: Results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24)[†]

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	6.32	n/a	n/d	n/a
T = 3 mo	n/d	n/a	6.19	n/a
T = 6 mo	n/d	n/a	6.87	10.98
T = 15 mo	6.59	4.27	6.5	5.01

Table 5: Results for Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25)[†]

	Glass		HDPE	
	% AI	% change	% AI	% change
T = 0	14.00	n/a	n/d	n/a
T = 3 mo	n/d	n/a	13.76	n/a
T = 6 mo	n/d	n/a	15.46	12.36
T = 15 mo	14.20	1.41	14.59	6.03

[†] MRID 48106201, pp 14-15.

The results for the manufacturing-use product (MP) are listed in Table 1. This product, Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20) has an active ingredient (a.i.) concentration of 100% listed on its label and two components listed as active ingredients on its CSF. **The data presented do not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their CSF. This must be addressed.**

The end-use products (EPs) analyzed in this study were stored and sampled from glass and HDPE containers only. The results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21) are listed in Table 2. The a.i. concentration listed on the Confidential Statement of Formula (CSF) for this product is 7.0%, with upper and lower certified limits of 7.35% and 6.65%, respectively. Measured concentrations in this study range from 5.89 to 6.81 percent a.i. Specifically, ending values (T = 15 months) are 6.13% for the glass container and 6.08% for the HDPE container. These values are below the lower certified limit for the a.i. **The registrant must explain these a.i. percentage values.**

The results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23) are listed in Table 3. The a.i. concentration listed on the CSF for this product is 15.0%, with upper and lower certified limits of 15.75% and 14.25%, respectively. The ending concentration for the HDPE container was within these limits at 14.41%. The ending a.i. concentration for the glass container was 14.07, which is below the lower certified limit. **The registrant must explain this value.**

The results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24) and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25) are listed in Tables 4 and 5, respectively. Both products show a net increase in a.i. concentration over the course of the study.

Nepeta cataria oils
PC Code: 004801

DP Nos: 378691; 378694; 378693; 378696; 378695
EPA File Symbol Nos.: 71654-20, -21, -23, -24, and -25

However, the starting concentrations of a.i. for both products was below the lower certified limit values listed on the CSF. **The registrant must explain these values.**

CLASSIFICATION: UNACCEPTABLE, but upgradable. The registrant demonstrate that the two active ingredients present in their TGAI are stable within the certified limits listed on their Confidential Statement of Formula CSF. The registrant must justify why sampling for each container type was not performed at each time interval. The registrant must also explain values lying outside the active ingredient certified limits.

Corrosion Characteristics

Observations of the samples and packaging used in the above study of Storage Stability lead the study authors to conclude that the test substance is not corrosive to packaging materials. Details of these observations were not included.

CLASSIFICATION: ACCEPTABLE, no additional data are required.

Data Evaluation Records (DERs) were not written for this review. For additional information on these Storage Stability and Corrosion Characteristics studies, please refer to MRID 48106201.

cc: G. Casciano, M. Adams, R. S. Jones, BPPD Science Review File, IHAD/ARS
G. Casciano, Biologist, FT, PY-S: 8/25/2010

DATA PACKAGE BEAN SHEET

Date: 07-Jun-2010

Page 1 of 2

Decision #: 434659

DP #: (378693)

NON PRIA

Parent DP #:

Submission #: 875464

*** Registration Information ***

Registration: 71654-23 - REFINED OIL OF NEPETA CATARIA 15% LOTION

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Menyon Adams MADAMS07

Sent Date: 27-May-2010

Calculated Due Date: 14-Sep-2010

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 004801, Nepeta cataria oils(15%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 07-Jun-2010

Due Back: _____

DP Ingredient: 004801, Nepeta cataria oils

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

07-Jun-2010

Last Possible Science Due Date: 06-Jul-2010

Team Name: RM 91

07-Jun-2010

Science Due Date: _____

Reviewer Name: Jones, Russell

07-Jun-2010

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attention Russ,
Please review the storage and stability submission.
Thanks

Due Date August 16, 2010

DP#: (378693)

*** Studies Sent for Review **

Decision#: (434659)

MRID	MRID Status	Citation Reference	Guideline
48106201		Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6320/Corrosion characteristics
48106200		E.I. du Pont de Nemours and Company (2010) Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. Transmittal of 1 Study.	
48106201		Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p.	830.6317/Storage stability

Receipt for Section 3

S: 875484

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Billable: ☒ Yes ☐ No

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY V

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 71654-23 Product Name: REFINED OIL OF NEPETA CATARIA 15% LOTIC

Override#:

Me Too Section3: Me Too Product Name:

Application Date: 21-May-2010

OPP Rec'd Date: 27-May-2010

Front End Date: 27-May-2010

Risk Manager Send Date: 27-May-2010

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

1 yr. storage stability and corrosion characteristics

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit



DuPont Chemicals and Fluoroproducts

May 21, 2010

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Refined Oil of *Nepeta cataria* technical; EPA Reg. No. 71654-20
Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 71654-23
Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 71654-21
Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 71654-25
Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 71654-24

Reference: OPPTS 830.6317 (Storage Stability)

Dear Ms. Hollis,

Please refer to the attached study, which was listed as a condition of issuance of the subject registrations.

Should there be any questions, please feel free to call or e-mail.. Thank you for your assistance with our applications.

Sincerely,

A handwritten signature in cursive script, appearing to read "Thomas C. McEntee".

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(978) 312-1160
(302) 695-6856



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

71654-23

Date of Issuance:

JUL 29 2009

NOTICE OF PESTICIDE:

Registration Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Conditional

Name of Pesticide Product:

Refined Oil of *Nepeta cataria*
7% Lotion

Name and Address of Registrant (include ZIP Code):

DUPONT CHEMICAL SOLUTION ENTERPRISE
P.O. BOX 80402
WIL MINGTON, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit a data package for the Guideline Study: OPPTS 830.6317 (Storage Stability), within 12 months from the date of issuance of this registration notice.
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-23.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

W. Michael McDavit

Date: 7-29-09

Michael McDavit, Associate Director
Biopesticides and Pollution
Prevention Division

CONCURRENCES

SYMBOL	7511P	7511P	7511P			
SURNAME	COLE	COLE	HOLIS			
DATE	7/28/09	7/28/09	7/28/09			

UN

STATES ENVIRONMENTAL PROTECT

AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

71654-23

Date of Issuance:

JUL 29 2009

NOTICE OF PESTICIDE:

____ Registration ____ Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Conditional

Name of Pesticide Product:

**Refined Oil of *Nepeta cataria*
7% Lotion**

Name and Address of Registrant (include ZIP Code):

DUPONT CHEMICAL SOLUTION ENTERPRISE
P.O. BOX 80402
WIL MINGTON, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

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1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit a data package for the Guideline Study: OPPTS 830.6317 (Storage Stability), within 12 months from the date of issuance of this registration notice.
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-23.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

W. Michael McDavit

Date: 7-29-09

CONCURRENCES

Michael McDavit, Associate Director
Biopesticides and Pollution
Prevention Division
SYMBOL
SURNAME
DATE

7511P 7511P 7511P
COLE HARRIS
7/28/09 7/28/09

EPA Form 8570-6
EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

14

Refined Oil of *Nepeta cataria* 15% Lotion

Insect Repellent Lotion
Repels Mosquitoes and Black Flies

ACTIVE INGREDIENT:

Refined Oil of <i>Nepeta cataria</i>	15.0%
Other Ingredients	85.0%
Total	100.0%

EPA Reg. No. 71654 - 21 [ER]

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in Eyes: <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for further treatment advice.
If Swallowed: <ul style="list-style-type: none">• Call Poison Control Center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything by mouth to an unconscious person
Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).
For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

ACCEPTED

JUL 29 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 71654-23

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs. Ask a doctor before using on children under 1 year of age.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes and Black Flies for up to 7 hours.

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds or freshly shaved skin,

To apply to face; apply to palms of hand and rub on skin. An adult must apply this product to children under ten years of age. Do not apply to children's hands.

For continued protection: Reapplication after six hours may be necessary.

After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Complete Outdoor protection (OPT)
- Guards the whole family (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) formula (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Contains (a) plant-based Active Ingredient, Refined Oil of *Nepeta cataria* (OPT)
- Plant based repellent Active Ingredient, Refined Oil of *Nepeta cataria* (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Contains plant extracts (OPT)
- Plant based ingredient (-do not settle for less efficacy) (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- For playing and relaxing outdoors (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)

- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

Refined Oil of *Nepeta cataria* 15% Lotion

Insect Repellent Lotion
Repels Mosquitoes and Black Flies

ACTIVE INGREDIENT:

Refined Oil of <i>Nepeta cataria</i>	15.0%
Other Ingredients	85.0%
Total	100.0%

EPA Reg. No. 71654 – 21 [ER]

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:

E.I. du Pont de Nemours and Company

PO Box 80402

Wilmington, DE 19880-0402

Net Contents: _____

ACCEPTED

JUL 29 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 71654-23

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing. Discontinue use and consult a doctor if irritation or rash occurs. Ask a doctor before using on children under 1 year of age.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes and Black Flies for up to 7 hours.

Apply liberally and evenly over dry, exposed skin. Do not apply over cuts, wounds or freshly shaved skin,

To apply to face; apply to palms of hand and rub on skin. An adult must apply this product to children under ten years of age. Do not apply to children's hands.

For continued protection: Reapplication after six hours may be necessary.

After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Complete Outdoor protection (OPT)
- Guards the whole family (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) formula (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Contains (a) plant-based Active Ingredient, Refined Oil of *Nepeta cataria* (OPT)
- Plant based repellent Active Ingredient, Refined Oil of *Nepeta cataria* (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Contains plant extracts (OPT)
- Plant based ingredient (-do not settle for less efficacy) (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- For playing and relaxing outdoors (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)

- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)



Re: Fw: Refined Oil of Nepeta cataria EPA File Symbols 71654 - ER and EG
Thomas C McEntee to: Raderrio Wilkins

07/22/2009 01:29 PM

Mr. Raderrio Wilkins,

Please substitute the attached 20090722 PDF files of the subject project to supersed the labels submitted July 14, 2009.

(See attached file: 20090722 7% Lotion Label .pdf) (See attached file: 20090722 15% Lotion Label .pdf)

incorporating the following revisions:

1. Repels Mosquitoes and Black Flies added below product name
2. Moved NET CONTENTS _____ to front page.
3. Re-positioned DIRECTIONS FOR USE heading and instruction to follow PRECAUTIONARY STATEMENTS section
4. DELETED: portions of the First Aid statement delaing with dermal contact; e.g. "IF A REACTION TO THIS PRODUCT IS SUSPECTED . . ."

'If a reaction to this product . . . " is suspected still appears in precautionary statements. Highlighted versions for comparison purpose.

(See attached file: 20090722 15% Lotion Label Highlighted.pdf) (See attached file: 20090722 7% Lotion Label Highlighted .pdf)

Tom McEntee
978 312 1136
978 335 8055 CELL

Wilkins.Raderrio@
epamail.epa.gov

07/14/2009 02:36
PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Raderrio Wilkins
<wilkins.raderrio@epa.gov>

Subject
Fw: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates
to the calenar year 2009 71654 - ER
and EG

Dear Mr. McEntee,

Please refer to the email below that included an attachment for the labels referenced above.



Re: Fw: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates to
the calenar year 2009 71654 - ER and EG
Thomas C McEntee to: Raderrio Wilkins

07/14/2009 05:18 PM

Mr. Raderrio Wilkins,

I am not sure that I understood all of the revisions.

Please accept the attached and let me know if there are any further
revisions required.

I have retained the OPT marketing claim "New!".

Thank you for your prompt attention to our applications.

(See attached file: 20090714 7% Lotion Label .pdf) (See attached file:
20090714 15% Lotion Label .pdf)

Tom McEntee
978 312 1136
978 335 8055 CELL

Wilkins.Raderrio@
epamail.epa.gov

07/14/2009 02:36
PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Raderrio Wilkins
<wilkins.raderrio@epa.gov>

Subject
Fw: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates
to the calenar year 2009 71654 - ER
and EG

Dear Mr. McEntee,

Please refer to the email below that included an attachment for
the labels referenced above.

Raderrio

----- Forwarded by Raderrio Wilkins/DC/USEPA/US on 07/14/2009 02:30 PM

From: Raderrio Wilkins/DC/USEPA/US

To: Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>

Cc: Raderrio Wilkins <wilkins.raderrio@epa.gov>, Andrew Bryceland/DC/USEPA/US@EPA

Date: 05/27/2009 05:25 PM

Subject: Re: Fw: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates to the calendar year 2009
71654 - ER and EG

Dear Mr. McEntee,,

Per your request, the Agency's Inert Ingredient Assessment Branch (IIAB) approved your application for a new non-food use inert ingredient clearance for [REDACTED], however, you have not complied with BPPD's request by submitting a new inert ingredient request petition to IIAB for the other three chemicals [REDACTED] as requested in BPPD's deficiency letter (dated 11/13/08). Furthermore, BPB is awaiting Dupont Chemical Solutions Enterprise's response to the Product Chemistry and Physical Property data deficiencies.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60 (PRIA 1) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, the PRIA decision date of July 31, 2009 precedes the 75 day date (May 17, 2009) for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. If applicable we will need to renegotiate the your pria due date.

Alternatively, you may withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about July 31, 2009. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact immediately on (703) 308-1259 with your response.

(See attached file: [revise per Label comments dated May 2009].pdf)

Sincerely

Raderrio Wilkins

Inert ingredient information may be entitled to confidential treatment

From: Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
To: Raderrio Wilkins/DC/USEPA/US@EPA
Date: 05/27/2009 01:21 PM
Subject: Fw: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action
Dates to the calenar year 2009 71654
- ER and EG

Mr. Raderrio Wilkins,

Can you let me know if everything is satisfactory for finalizing notice
of
registration by the re-negotiated dates.

Thanks for your help.

Tom McEntee
978 312 1136
978 335 8055 CELL
----- Forwarded by Thomas C McEntee/AE/DuPont on 05/27/2009 01:21 PM

Thomas C
McEntee/AE/DuPont

To 11/26/2008 12:44
Hollis.Linda@epamail.epa.gov@DUPONT
PM _MHUB

cc wilkins.raderrio@epa.gov

Subject Re: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates
to the calenar year 2009 (Document
link: Thomas C McEntee)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: June 30, 2009

SUBJECT: Science Review in Support of the Registration of Refined Oil of *Nepeta cataria* 15% Lotion and Refined Oil of *Nepeta cataria* Lotion 7%, Containing 15% and 7% Refined Oil of *Nepeta cataria* As Its Active Ingredients.

Decision Number:	371862, 372756
DP Number:	365995, 365996
EPA File Symbol Number:	71654-ER, 71654-EG
Chemical Class:	Biochemical
PC Code:	004801
CAS Number:	8023-84-5
Tolerance Exemptions:	Non-food Use
MRID Numbers:	N/A

FROM: Jacob Moore, Chemist /s/ 07/07/09 *Paul J. H. Moore* 7/7/09
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

In response to the request for additional information relayed in letters from BPPD to the registrant dated 10/17/07 & 4/16/08, the registrant has submitted revised CSF dated 06/12/09 and MSDS for all inert ingredients.

Refined Oil of *Nepeta cataria*
PC Code: 004801

DP Number: 365995, 365996
EPA Reg. No.: 71654-ER, -EG

RECOMMENDATIONS AND CONCLUSIONS

1. CSF (06/12/09) is **ACCEPTABLE**. All inert ingredients are cleared and have appropriate PC Codes.
2. Product chemistry data are **ACCEPTABLE**. No additional data are required. A year long storage stability study (OPPTS 830.6317) is ongoing and will be submitted upon completion.

Product Chemistry

MSDS were submitted for all inert ingredients contained within the products. In the administrative materials, the registrant notes that a year long storage stability study is in progress and will be submitted upon completion. All other product chemistry data requirements have been successfully addressed.

cc: J. Moore, R. Wilkins, BPPD Science Review File, IHAD/ARS
J. Moore, ET, PY-S: 07/07/09

**Document Processing Desk (RESUB)
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202**

E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL 402/3442A)
P. O. Box 80402
Wilmington, DE 19880-0402

- Cover Letter 2 pages
- Transmittal Document this page
- 15% Lotion CSF (EPA Form 8570-4) 2pages
- 7% Lotion CSF (EPA Form 8570-4) 2 pages
- Portfolio of MSDSs for inert ingredients 60 pages

Registration Details

Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY

Risk Mgr: RM 91 Biologicals & Pollution Prevention Division, PM Team 91 ...

Organization: AD / RMB2 ...

Current Status: Under Review (08-Dec-2006)

Reg. Number: 71654-EG Pesticide Type: Biochemical High Exposure? ☐

Use Type: EP Signal Word: Caution

Repack: ☐ Yes ☒ No Latest Approved Label:

NPIC Phone: ☐ Yes ☒ No No Ingredient? ☐ WPS Written Notification: ☐ Yes ☒ No

Related Products Restricted Use 12 Reg. Expiration Date

Use Patterns Transfer History Toxicology Mode Of Action FR Notice Receipts

Product Name Ingredient Formulation Property Pesticide Category Permitted State

Product Name	Name Status
REFINE OIL OF NEPETA CATARIA 7% LOTION	Active

WPS-PPE

Label Image

Container Info

Tracking

Status

Sites/Pests

CSF

Data Requirements

Generate Rqmts

Inert Ingredients

Subm # 853064



DuPont Chemical Solutions Enterprise

June 12, 2009

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

2 Submissions
Included
Here

71654-ER
71654-EG

Subject: Resubmission -- New Pesticide Application for Registration
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER ✓
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG ✓

Reference: Dupont Submission of May 8, 2008
EPA Deficiency Letter of November 13, 2008

Dear Ms. Hollis,

Following e-mail communication from Mr. Raderrio Wilkins on May 25, 2009, it appears that there is a disconnect concerning compliance with the chemistry deficiencies for the subject products. The deficiencies were addressed in my submission of May 8, 2008. Please refer to the following transmittal documents and attachments for each of the subject end-use product resubmissions. Detailed responses to your November 13, 2008 letter are as follows:

I. CSF

- a. CAS Registry Number [REDACTED] has been added to the CSF.
- b.1. CAS Registry Number for [REDACTED] has been corrected to [REDACTED]
- b.2. [REDACTED] has been removed from the formula.
- c. The CAS Number 8023-84-5 has been assigned to the active ingredient consistent with the NPIRS designation.
- d. [REDACTED] has been added to the list of allowed inerts by the manufacturer through submission to the IIAB. [REDACTED] has been removed from the legacy formula and replaced with an equal quantity of the inert [REDACTED] has been eliminated. The mixture [REDACTED] has been deleted and in its place substituted [REDACTED], which does not contain the minor component, [REDACTED]. In summary, the lotion now contain only ingredients that are all on EPA's list of allowed ingredients.
- e.1. Chemical nomenclature of [REDACTED] has been corrected.

e.2. [REDACTED] has been added to the CSFs, which is consistent with the nomenclature of the, **Ingredients Permitted in Pesticide Products**, <http://www.epa.gov/opprd001/inerts/lists.html>.

f. The quantity stated on CSF dated June 12, 2009 is correct. MRID number 47003301 has been superseded.

g. Supplier identified on CSF dated June 12, 2009 is correct.

h. CSF blocks #5 and #6 have been completed.

II. PRODUCT CHEMISTRY

a. An increase in the quantity of one chemical of the active ingredient component is improbable and is attributed to the limitations of the analytical method when applied to the formulation. The active ingredient is a complex mixture and quantitating the components is an analytical challenge. **A year-long storage stability study is in progress, which will be submitted upon completion.**

b. The complete portfolio of MSDSs is attached (60 pages)

c. Quality Control: Each lot is visually examined for typical properties. A sample is taken for specific gravity measurement and is analyzed for active ingredient following the Enforcement Analytical Method; (MRID 470033020).

d. Its not clear that "other" components degrade. The submitted data is an interim study. A one-year guideline study is in progress. The magnitude of "degradation" appears to be minor and is only reflected in the **dihydronepetalactone 3** levels. The analysis has been challenging and refinements to applying the method to formulated lotions have been made since submitting the cited data.

e. Further submissions to IIA because as discussed in I.d above, the formulations have been revised so that all of the ingredients are on the list of allowable inert ingredients.

III. PHYSICAL PROPERTIES

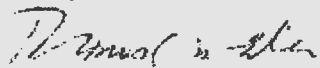
Oxidation-Reduction: Not Required – the formula does not contain an oxidizing-reducing agent. (Ref. 40CFR158.190; note #5)

Chemical Incompatibility: Not Required – the formula is a ready-to-use end-use formula which does not require dilution or mixing with other chemicals.

Explosibility: Not Required – the formula is not potentially explosive. (Ref. 40CFR158.190; note #7)

Should there be any questions, please feel free to call or e-mail.. Thank you for your assistance with our applications.

Sincerely,



Thomas C. McEntee

Product Registration Manager

Thomas.C.McEntee@usa.dupont.com

(302) 695-6856

DATA PACKAGE BEAN SHEET

Date: 10-Jun-2009

Page 1 of 1

Decision #: 372756

DP #: (365996)

PRIA

Parent DP #:

Submission #: 828999

*** Registration Information ***

Registration: 71654-EG - REFINE OIL OF NEPETA CATARIA 7% LOTION

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Andrew Bryceland ABRYCELA

Sent Date: 14-May-2008

Calculated Due Date: 30-May-2008

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (B60.4) NEW AI;NON-FOOD USE;MICROBIAL/BIOCHEMICAL;NO FEE: LINKED TO A PRIA.

Ingredients: 004801, Nepeta cataria oils(7%)

*** Data Package Information ***

Expedite: ☒ Yes ☐ No

Date Sent: 10-Jun-2009

Due Back: _____

DP Ingredient: 004801, Nepeta cataria oils

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☐ Yes ☒ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

10-Jun-2009

Last Possible Science Due Date: 05-Aug-2008

Team Name: RM 91

10-Jun-2009

Science Due Date: _____

Reviewer Name: Moore, Jacob

10-Jun-2009

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

Can be printed on its own page

*** Data Package Instructions ***

Jacob,

PRIA due date 7/31/09. Please expedite this review. This is a review of a new CSF. It was not dated. This is a response to two deficiency letter dated 10/17(16)/07 and 4/16/08, refer to the registrant's 5/8/08 cover letter. Raderrio also included an Agency letter dated 11/13/09. According to the hand written note on the 11/13/09 Agency letter is was sent to the registrant as a "follow up." Please review the CSF and the registrant's response and determine if the CSF is acceptable and if the registrant's response. According to Raderrio, one of the problems was that not all of the inert ingredients were cleared. In your review please make sure that all of the inerts are cleared. Please address your review memo to Raderrio. Attached are:

5/8/08 Registrant's cover letter

New CSF (no date)

10/16/07, 4/16/08, & 11/13/08 Agency letters

Old CSF dated 10/19/06

Email traffic between the registrant and Raderrio as FYI.

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

May 8, 2008

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Resubmission -- New Pesticide Application for Registration
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG

Reference: EPA letter of October 17, 2007
EPA letter of April 16, 2008
EPA-Dupont November 8, 2007 meeting

Please refer to the following transmittal documents and attachments for each of the subject end-use product resubmissions. I believe these documents and the February 28, 2008 resubmission on the TGAI; EPA File Symbol 71654-EN along with data submitted on one inert ingredient address all of the remaining data requirements.

DuPont is offering a PRIA due date of October 31, 2008 which allows six months for EPA review of all of the items.

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695 6856

TRANSMITTAL DOCUMENT

Attention:

Document Processing Desk (RESUB)
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

NAME AND ADDRESS OF SUBMITTER

E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL 402/3442A)
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Resubmission: New Pesticide Registration End-Use Product

"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG

Transmittal Date: **May 8 , 2008**

Transmittal Material:

Volume 1 Administrative Materials

- Cover Letter	1 page
- Transmittal Document	1 pages
- 15% Lotion CSF (EPA Form 8570-4)/Check Sheet	3 pages
- 7% Lotion CSF (EPA Form 8570-4)/Check Shteet	3 pages
- Data Matrix EPA form (8570-35)	2 pages
- Cross Reference: EPA comments to corrections	1 page

Volume 2A Chemistry

Product Identity and Composition; 830.1100 Description of Starting Materials, Production and Formulation Process; 830.1200; April 23, 2008 78 pages
McEntee, Thomas C.; E.I. duPont de Nemours and Company.

EPA Letter Oct. 16, 2007 page/comment

“Refined Oil of *Nepeta cataria*” 15% Lotion; EPA File Symbol 71654-ER
“Refined Oil of *Nepeta cataria*” 7% Lotion; EPA File Symbol 71654-EG

Page 2/a.	
Page 2/b.	
Page 3/c.	
Page 3/d.	
Page 3/e.	
Page 3/f.	CSF dated April 23, 2008 is correct. Refer to attached Volume 2 for revised guideline study 880.1100 and 880.1200 (supersede 47003301)
Page 3/g.	CSF and Volume 2 revised guideline study 880.1100 and 880.1200 (supersede 47003301)
Page 3/h.	CSF blocks #5 and #6 completed
Page 3/IIa.	One-Year Storage Stability study (830.6313) – Time 0 results show zero of the named component as expected. Study to be submitted at the end of the one-year cycle.
Page 3/IIb.	Refer to Volume 2; page 10 thru page 78
Page 3/IIc.	After step A2.3 (Refer to Volume 2); Each lot is visually examined for typical properties. A sample is taken for specific gravity measurement and is analyzed for active ingredient following the Enforcement Analytical Method; (MRID 470033020).
Page 3/IId.	Its not clear that “other” components degrade. The submitted data is an interim study. A one-year guideline study is <u>in progress</u> . The magnitude of “degradation” appears to be minor and is only reflected in the dihydronepetalactone 3 levels. The analysis has been challenging and refinements to applying the method to formulated lotions have been made since submitting the cited data.
Page 3-4/IIe	
Page 4/III.a.	<u>Oxidation-Reduction:</u> Not Required – the formula does not contain an oxidizing-reducing agent. (Ref. 40CFR158.190; note #5) <u>Chemical Incompatability:</u> Not Required – the formula is a ready-to-use end-use formula which does not require dilution or mixing with other chemicals. <u>Explodability:</u> Not Required – the formula is not potentially explosive. (Ref. 40CFR158.190; note #7)
Page 4/IIIb.	One-year guideline storage stability and corrosion characteristics are in-progress.
Page 5/IV.	Efficacy study comments were addressed in the February 28, 2008 submission on the TGAI.



Fw: 71654 - ER and EG
Raderrio Wilkins to: Linda Hollis
Cc: Andrew Bryceland

06/09/2009 12:34 PM

Linda and Andy

Mr McEntee responded to my follow up email (dated 5/27/09) stating he responded via e-mail on May 5, 2008, whereby he had attached a copy of a response to the earlier chemistry deficiencies. The only email Mr. McEntee sent was on May 9, 2008 to Karen Angula requesting an inerts re-qualification for the two products referenced above. On May 28, 2008, the registrant emailed you and I a resubmitted response which you responded saying, "It has been noted that this is a courtesy copy. The Agency will act on an official copy submitted to the document processing center per your last email to him".

On November 31, 2009, BPB provided Mr. McEntee with a status report of his pending products (71654-EN (TGAI) and the four (4) End Use 71654- EU, EL, ER- and EG). On November 13, 2008, BPB sent a formal letter reiterated all the deficiencies that were identified in pervious letters and email correspondence. The registrant renegotiated their PRIA Date from 11/30/08 to 7/31/09 to address the data deficiencies. OPPIN is showing three unlinked submission that came into the Agency but were never assigned. Linda, if your schedule permits, I would like to meet with you today for fifteen minutes to discuss the next course of action.

- Copy of \$ old CSP

EPA-PRISM Main - Connected as rwilkins @ PRISM10P [Basic User] - [Explore Registrations]

Tracking Create/Edit Collections Utilities Query Tool Portal Help Exit

Reg Number: 71654-ER Reg. Type: Product Registration - Section 3 Status: Under Review (02-Nov-2008)

Name: REFINED OIL OF NEPETA CATARIA 15% LOTION <View Registration Detail>

(New Receipts)

S:	Submission Type	OPP Rec'd Date	Resubmission	Description
<input type="radio"/> 809186	Pending Product Amendment	24-Apr-2007	<input type="radio"/> Yes <input checked="" type="radio"/> No	3 supplements to previous efficacy studies
<input type="radio"/> 828816	Miscellaneous Receipt	02-May-2008	<input type="radio"/> Yes <input checked="" type="radio"/> No	
<input checked="" type="radio"/> 828997	Miscellaneous Receipt	13-May-2008	<input type="radio"/> Yes <input checked="" type="radio"/> No	response to EPA letter of 10/17/07, EPA letter

...Decisions...

- Data Requirements
 - D: Pending; 371862; 71654-ER;B60.0;NEW AI;N
 - 75-Day Letters
 - S: 810568 5/21/2007; New Registration; 71654-ER
 - S: 803485 1/5/2007; New Registration; 71654-ER
 - S: 802300 12/8/2006; New Registration; 71654-ER
 - S: 800970 11/1/2006; New Registration; 71654-ER

Ready

Sincerely,
Raderrio Wilkins

----- Forwarded by Raderrio Wilkins/DC/USEPA/US on 06/09/2009 10:36 AM -----

From: Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
To: Raderrio Wilkins/DC/USEPA/US@EPA
Date: 05/29/2009 04:28 PM
Subject: 71654 - ER and EG

Mr. Raderrio Wilkins,

I am forwarding my e-mail from May 5, 2008, where I had attached a copy of a response to the earlier chemistry deficiencies. I am also attaching an e-copy of revised CSF's (April 22, 2008) for the product which negate the

comments from the chemistry review.

In summary, the CSF used substitute ingredients which are on the EPA list of inerts and have the same functional properties and are chemically substantially similar.

Please let me know if these revised CSFs would be acceptable. If you do not find this submission from May 8, 2008 in the files, I will re-submit.

Thank you for your help and have a fine weekend.

(See attached file: 20080422 15% HCO Lotion 8570-4.doc) (See attached file: 20080422 7% HCO Lotion 8570-4 2 pages F .doc)

Tom McEntee
978 312 1136
978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/29/2009 04:23 PM -----

Thomas C
McEntee/AE/DuPont

05/28/2008 10:55
AM

To
Hollis.Linda@epamail.epa.gov@DUPONT
_MHUB,
Wilkins.Raderrio@epamail.epa.gov
cc

Subject
Re: Resubmission of Information
71654 - ER and EG (Document link:
Thomas C McEntee)

(See attached file: 20080528 Resend cover letter inert Lotion
substitutue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA DER 9/19/07. Following the November 20067 meeting with you, the formulas were revised to substitute chemically and functionally equivalent ingredients which are on EPA's list with the exception of one inert. This inert is the subject of the submission to IIRB on April 30, 2008.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

05/13/2008 11:53

To
Thomas C McEntee/AE/DuPont@DuPont,

AM

Wilkins.Raderrio@epamail.epa.gov

cc

Subject

Re: Resubmission of Information
71654-EN, ER, EG and EL

I believe that your submission was submitted late in addition to the fact that there were deficiencies outlined in our letter which you have not addresses in your resubmission. I am unclear as to your involvement with the inerts group for clearance however the information as resubmitted thus far remain deficient. You may either renegotiate or we will elect to issue a can not grant. Alternatively, you can withdraw.

-----Original Message-----

From: Thomas C McEntee

To: Raderrio Wilkins

To: Linda Hollis

Sent: May 13, 2008 11:06 AM

Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

Thank you for your telephone call. I am still trying to confirm that IIRB has received the documents on the unlisted inert from our supplier, which affect the review cycle for the end-use formulated lotions.

Returning to the previous negotiated date for the Nepeta catariaTechnical and Manufacturing Use Product (71654- EN) [EPA letter of Nov. 8, 2007], the PRIA date was May 30, 2008. We met the target date of February 2008 for re-submission. Extension of the PRIA date out to November for the technical registration does not seem justified.

Please let me know of any developments which are a basis for your suggestion of a November date for the technical registration.

Thank you for your attention to our applications.

Tom McEntee

302 695 6856

978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM

Thomas C

McEntee/AE/DuPont

To

Inert ingredient information may be entitled to confidential treatment

05/06/2008 05:54 Hollis.Linda@epamail.epa.gov@DUPONT
PM _MHUB
cc wilkins.raderrio@epa.gov
Subject
Re: Fw: Resubmission of
Information 71654-EN, ER, EG and EL
(Document link: Thomas C McEntee)

Ms. Linda Hollis,

Thank you for your e-mails. I will be completing the submissions on the end-use formulas this week.

This is to confirm that I will request a renegotiated action date for the applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta cataria Technical and Manufacturing Use Product"
EPA

File Symbol 71654-EN

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU

"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007

EPA letter of August 29, 2007

EPA letter of April 16, 2008

EPA-Dupont November 8, 2007 meeting

(See attached file: [REDACTED].pd

-----Original Message Truncated-----

to -----\Sent by EPA Wireless E-Mail Services.

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20080422 15% HCD Lotion 8570-4.doc 20080422 7% HCD Lotion 8570-4 2 pages F.doc



20080528 Resend cover letter inert Lotion substitue.pdf



71654 - ER and EG
Thomas C McEntee to: Raderrio Wilkins

05/29/2009 04:28 PM

History: This message has been forwarded.

Mr. Raderrio Wilkins,

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Tom McEntee
978 312 1136
978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/29/2009 04:23 PM -----

Thomas C
McEntee/AE/DuPont

05/28/2008 10:55
AM

To
Hollis.Linda@epamail.epa.gov@DUPONT
_MHUB,
Wilkins.Raderrio@epamail.epa.gov
cc

Subject
Re: Resubmission of Information
71654 - ER and EG (Document link:
Thomas C McEntee)

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf)

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Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

05/13/2008 11:53 AM

To
Thomas C McEntee/AE/DuPont@DuPont,
Wilkins.Raderrio@epamail.epa.gov
cc

Subject
Re: Resubmission of Information
71654-EN, ER, EG and EL

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To: Linda Hollis
Sent: May 13, 2008 11:06 AM
Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

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Thank you for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM

Thomas C
McEntee/AE/DuPont

To
05/06/2008 05:54 Hollis.Linda@epamail.epa.gov@DUPONT
PM _MHUB
cc
wilkins.raderrio@epa.gov
Subject
Re: Fw: Resubmission of
Information 71654-EN, ER, EG and EL
(Document link: Thomas C McEntee)

Ms. Linda Hollis,

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This is to confirm that I will request a renegotiated action date for the applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta cataria Technical and Manufacturing Use Product"
EPA

File Symbol 71654-EN

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU

"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007

EPA letter of August 29, 2007

EPA letter of April 16, 2008

EPA-Dupont November 8, 2007 meeting

(See attached file: [REDACTED].pd

-----Original Message Truncated-----

to -----\Sent by EPA Wireless E-Mail Services.

Inert ingredient information may be entitled to confidential treatment

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20080422 15% HCO Lotion 8570-4.doc 20080422 7% HCO Lotion 8570-4 2 pages F.doc



20080528 Resend cover letter inert Lotion substitute.pdf



Re: Fw: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates to the calendar year 2009 71654 - ER and EG

Raderrio Wilkins to: Thomas C McEntee

05/27/2009 05:24 PM

Cc: Raderrio Wilkins, Andrew Bryceland

Dear Mr. McEntee,,

Per your request, the Agency's Inert Ingredient Assessment Branch (IIAB) approved your application for a new non-food use inert ingredient clearance for [REDACTED], however, you have not complied with BPPD's request by submitting a new inert ingredient request petition to IIAB for the other three chemicals [REDACTED] as requested in BPPD's deficiency letter (dated 11/13/08). Furthermore, BPB is awaiting Dupont Chemical Solutions Enterprise's response to the Product Chemistry and Physical Property data deficiencies.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60 (PRIA 1) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, the PRIA decision date of July 31, 2009 precedes the 75 day date (May 17, 2009) for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. If applicable we will need to renegotiate the your pria due date.

Alternatively, you may withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about July 31, 2009. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact immediately on (703) 308-1259 with your response.

Sincerely

Raderrio Wilkins

Thomas C McEntee

Mr. Raderrio Wilkins, Can you let me know if e...

05/27/2009 01:21:29 PM

From: Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>
To: Raderrio Wilkins/DC/USEPA/US@EPA
Date: 05/27/2009 01:21 PM
Subject: Fw: Refined Oil of Nepeta cataria -- Renegotiated PRIA Action Dates to the calendar year 2009 71654 - ER and EG

Mr. Raderrio Wilkins,

Can you let me know if everything is satisfactory for finalizing notice of registration by the re-negotiated dates.

Thanks for your help.

Tom McEntee

978 312 1136

978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/27/2009 01:21 PM -----

Thomas C
McEntee/AE/DuPont

11/26/2008 12:44
PM

To
Hollis.Linda@epamail.epa.gov@DUPONT
_MHUB

cc
wilkins.raderrio@epa.gov

Subject
Re: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates
to the calenar year 2009(Document
link: Thomas C McEntee)

Ms. Linda Hollis,

This will confirm the negotiated dates are in calenar year 2009 as you have detailed below.

Tom McEntee

302 695 6856

978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

11/26/2008 12:07
PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc

wilkins.raderrio@epa.gov
Subject

Re: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates

Thank you, but there are some errors. The dates reflect year 2008. The dates should be the following:

71654-EN December 5, 2008

71654-EL and EU March 31, 2009

71654-EG and ER July 31, 2009 with the understanding that the Agency may likely to renegotiate again if the the Agency is not in receipt of all of the missing information, to include submission of the inert information to the Registration division by February 28, 2009.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

11/26/2008 12:00
PM

Linda Hollis/DC/USEPA/US@EPA To
cc
Raderrio Wilkins/DC/USEPA/US@EPA
Subject
Refined Oil of Nepeta cataria --
Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the need to renegotiate PRIA dates for the following applications for registration.

File Symbol	Product	Date	
71654-EN	Technical	December 5, 2008	(accomodate review of new active ingredient fact sheet)
71654-ER	15% Lotion	July 31, 2008	(acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate)
71654-EG	7% Lotion	July 31, 2008	(same as 71654-EG)

71654-EL 15% Liquid March 31, 2008 (resolve disconnect on
acute toxicology series)
71654-EU 7% Liquid March 31, 2008 (resolve disconnect on
acute toxicology series from 71654-EL)
All (re-review MRID
47362603 -
Supplemental Efficacy Explanations; after the fact HSRB upgrades)

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee
302 695 6856
978 335 8055 CELL

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 29 APRIL 2009

SUBJECT: Refined Oil of *Nepeta cataria* – Assessment of Toddler Hand-to-Mouth Exposure to Refined Oil of *Nepeta cataria* (Catnip) Applied Dermally as an Insect Repellent.

PC Code: 004801
MRID No.: None
Petition No.: None
Assessment Type: ORE
TXR No.: None, Number, or See Table

DP Barcode: D364141
EPA File Symbol 71654-EG, -ER
Regulatory Action: Section 3
Reregistration Case No.: None
CAS No.: None

FROM: Mark I. Dow, Ph.D., Biologist *MIDow*
Alternate Risk Integration Assessment Team (ARIA)
Risk Integration Minor Use & Emergency Response Branch (RIMUERB)
Registration Division (RD) 7505P

THROUGH: John C. Redden, ARIA Team Leader *JCR*
RIMUERB/RD 7505P

TO: Raderrio Wilkins, Risk Manager
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division 7511P

INTRODUCTION

Under provisions in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, the E.I. du Pont de Nemours and Company has requested registration of refined oil of *Nepeta cataria* for use as a dermal topical application as an insect repellent. Two products are proposed: a 7.0 % active ingredient (ai) lotion and a 15.0 % ai lotion.

The Registration Division (RD) has been requested to assess toddler hand-to-mouth exposure that might result from use of the formulation per label directions for use.

The risk assessment techniques used in this document are those that have been developed and refined by the HED/Office of Pesticide Programs' Science Policy Council for Exposure (ExpoSAC). RD herein utilizes the same techniques as are HED's standard operating procedures (SOP).

USE PATTERN SUMMARY

According to draft product labeling for the 7.0 % and 15.0 % lotion formulations, directions for use include: "Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults [sic] hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands." The label also directs: "Do not apply over cuts or damaged skin." "Do not allow children to handle the product or apply it to themselves."

Label claims include protection from or repellency to "mosquitoes", "black flies", "biting flies" and "a range of biting insects."

DISCUSSION

As noted earlier, the assessment techniques utilized are derived from Health Effects Division (HED) standard procedure. However, there are data utilized herein that are taken from two documents from the Biopesticides and Pollution Prevention Division (BPPD): (1. "BIOPESTICIDES REGISTRATION ACTION DOCUMENT – Refined Oil of *Nepeta casaria* [sic] Hydrogenated Catmint Oil (HCO)" L. Hollis et al., 28 NOV 2008 and 2. Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products", DP Code 338556, 339493, 339547, R. Gardner, 10 OCT 2007).

The refined oil is derived from the plant species *Nepeta cataria* commonly known as catnip. According to Hollis et al. (2008), Refined Oil of *Nepeta cataria* is classified in Acute Toxicity Category III for acute oral toxicity and primary eye irritation and in Acute Toxicity Category IV for acute dermal toxicity, acute inhalation toxicity and skin irritation. It is not a dermal sensitizer.

In Gardner, 2007, a dermal application rate is derived from performance dosimetry studies. The application rate is 0.378 mg active ingredient/cm² (of skin). Gardner also identified an acute (incidental) oral toxicological endpoint that is used here to assess toddler oral hand-to-mouth exposure. The endpoint is identified from an acute neurotoxicity study in the rat. The No Observable Adverse Effect Level (NOAEL) is 40 mg/kg. The effects seen were decreased motor activity on the day of dosing in males and females (MRID 45977409).

The risk assessment technique used by RD is modified from the HED "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" 9.2.2

7

“Postapplication Potential Dose Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Pets from Hand-to-mouth Transfer.” (18 DEC 1997). The modification is to account for the label directions which indicate reapplication may be necessary after 6 hours (i.e., 2 treatments/day) and the occurrence of 1 Hand-to-Mouth event/treatment. Thus, the factors used for assessment are:

$$\text{PDR} = (\text{Rate} * \text{Dis} * \text{SA} * \text{FQ} * \text{EX} * \text{TR})/\text{BW}$$

PDR = Potential Dose Rate (mg/kg bw/day)
 Rate = Rate of application (0.387 mg ai/cm²/event)
 Dis = Per cent dislodgeable residue (unitless 5.0) biologically available
 SA = Surface area toddler first 3 digits (20 cm²)
 FQ = Frequency of Hand to Mouth events (1 Event/treatment)
 EX = Saliva extraction factor (% unitless = 50.0)
 TR = Number treatments (2 treatments/day).

NOAEL = No Observable Adverse Effect Level (40 mg/kg bw/day)

MOE = Margin of Exposure (NOAEL/PDR).

$$0.378 \text{ mg ai/cm}^2/\text{treatment} * 0.05 (\%) * 20 \text{ cm}^2 * 1 \text{ event/treatment} * 0.50 (\%) * 2 \text{ events/day} \div 15 \text{ kg bw} = 0.0252 \text{ mg/kg bw/day}$$

$$\text{MOE} = \text{NOAEL}/\text{ADD} \text{ thus } 40 \text{ mg/kg bw/day}/0.0252 \text{ mg/kg bw/day} = 1,587.$$

CONCLUSIONS

The Agency's level of concern is for Margins of Exposure < 100. Since the estimated MOE is > 100, the proposed use does not exceed the level of concern. The factors used for risk assessment are considered conservative (protective) in terms of the estimated rate of application, estimated amount of available dislodgeable residue and estimated amount of extraction by saliva. Since efficacy data indicate effect times of 6 hours, it is expected that the formulation is not easily removed from the skin's surface.

cc:M.Dow(RIMUERB)
 RDI:J. Redden,
 M.I.Dow:S7824:PY1:(703)305-5533:RIMUERB:7505P



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

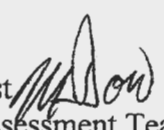
MEMORANDUM

DATE: 29 APRIL 2009

SUBJECT: Refined Oil of *Nepeta cataria* – Assessment of Toddler Hand-to-Mouth Exposure to Refined Oil of *Nepeta cataria* (Catnip) Applied Dermally as an Insect Repellent.

PC Code: 004801
MRID No.: None
Petition No.: None
Assessment Type: ORE
TXR No.: None, Number, or See Table

DP Barcode: D364141
EPA File Symbol: 71654-EG, -ER
Regulatory Action: Section 3
Reregistration Case No.: None
CAS No.: None

FROM: Mark I. Dow, Ph.D., Biologist 
Alternate Risk Integration Assessment Team (ARIA)
Risk Integration Minor Use & Emergency Response Branch (RIMUERB)
Registration Division (RD) 7505P

THROUGH: John C. Redden, ARIA Team Leader 
RIMUERB/RD 7505P

TO: Raderrio Wilkins, Risk Manager
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division 7511P

INTRODUCTION

Under provisions in Section 3 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, the E.I. du Pont de Nemours and Company has requested registration of refined oil of *Nepeta cataria* for use as a dermal topical application as an insect repellent. Two products are proposed: a 7.0 % active ingredient (ai) lotion and a 15.0 % ai lotion.

The Registration Division (RD) has been requested to assess toddler hand-to-mouth exposure that might result from use of the formulation per label directions for use.

The risk assessment techniques used in this document are those that have been developed and refined by the HED/Office of Pesticide Programs' Science Policy Council for Exposure (ExpoSAC). RD herein utilizes the same techniques as are HED's standard operating procedures (SOP).

USE PATTERN SUMMARY

According to draft product labeling for the 7.0 % and 15.0 % lotion formulations, directions for use include: "Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults [sic] hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands." The label also directs: "Do not apply over cuts or damaged skin." "Do not allow children to handle the product or apply it to themselves."

Label claims include protection from or repellency to "mosquitoes", "black flies", "biting flies" and "a range of biting insects."

DISCUSSION

As noted earlier, the assessment techniques utilized are derived from Health Effects Division (HED) standard procedure. However, there are data utilized herein that are taken from two documents from the Biopesticides and Pollution Prevention Division (BPPD): (1. "BIOPESTICIDES REGISTRATION ACTION DOCUMENT – Refined Oil of *Nepeta casaria* [sic] Hydrogenated Catmint Oil (HCO)" L. Hollis et al., 28 NOV 2008 and 2. Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products", DP Code 338556, 339493, 339547, R. Gardner, 10 OCT 2007).

The refined oil is derived from the plant species *Nepeta cataria* commonly known as catnip. According to Hollis et al. (2008), Refined Oil of *Nepeta cataria* is classified in Acute Toxicity Category III for acute oral toxicity and primary eye irritation and in Acute Toxicity Category IV for acute dermal toxicity, acute inhalation toxicity and skin irritation. It is not a dermal sensitizer.

In Gardner, 2007, a dermal application rate is derived from performance dosimetry studies. The application rate is 0.378 mg active ingredient/cm² (of skin). Gardner also identified an acute (incidental) oral toxicological endpoint that is used here to assess toddler oral hand-to-mouth exposure. The endpoint is identified from an acute neurotoxicity study in the rat. The No Observable Adverse Effect Level (NOAEL) is 40 mg/kg. The effects seen were decreased motor activity on the day of dosing in males and females (MRID 45977409).

The risk assessment technique used by RD is modified from the HED "Standard Operating Procedures (SOPs) for Residential Exposure Assessments" 9.2.2

“Postapplication Potential Dose Among Toddlers from Incidental Nondietary Ingestion of Pesticide Residues on Pets from Hand-to-mouth Transfer.” (18 DEC 1997). The modification is to account for the label directions which indicate reapplication may be necessary after 6 hours (i.e., 2 treatments/day) and the occurrence of 1 Hand-to-Mouth event/treatment. Thus, the factors used for assessment are:

$$\text{PDR} = (\text{Rate} * \text{Dis} * \text{SA} * \text{FQ} * \text{EX} * \text{TR})/\text{BW}$$

PDR = Potential Dose Rate (mg/kg bw/day)
 Rate = Rate of application (0.387 mg ai/cm²/event)
 Dis = Per cent dislodgeable residue (unitless 5.0) biologically available
 SA = Surface area toddler first 3 digits (20 cm²)
 FQ = Frequency of Hand to Mouth events (1 Event/treatment)
 EX = Saliva extraction factor (% unitless = 50.0)
 TR = Number treatments (2 treatments/day).

NOAEL = No Observable Adverse Effect Level (40 mg/kg bw/day)

MOE = Margin of Exposure (NOAEL/PDR).

$$0.378 \text{ mg ai/cm}^2/\text{treatment} * 0.05 (\%) * 20 \text{ cm}^2 * 1 \text{ event/treatment} * 0.50 (\%) * 2 \text{ events/day} \div 15 \text{ kg bw} = 0.0252 \text{ mg/kg bw/day}$$


$$\text{MOE} = \text{NOAEL}/\text{ADD} \text{ thus } 40 \text{ mg/kg bw/day}/0.0252 \text{ mg/kg bw/day} = 1,587.$$

CONCLUSIONS

The Agency's level of concern is for Margins of Exposure < 100. Since the estimated MOE is > 100, the proposed use does not exceed the level of concern. The factors used for risk assessment are considered conservative (protective) in terms of the estimated rate of application, estimated amount of available dislodgeable residue and estimated amount of extraction by saliva. Since efficacy data indicate effect times of 6 hours, it is expected that the formulation is not easily removed from the skin's surface.

cc:M.Dow(RIMUERB)
 RDI:J. Redden,
 M.I.Dow:S7824:PY1:(703)305-5533:RIMUERB:7505P



Re: Catnip (EPA File Symbols 71654-EG and ER) 
Raderrio Wilkins to: Linda Hollis

04/08/2009 12:41 PM

Linda,

To date, IIAB is not in receipt of any new inert ingredient requests, petitions or correspondences regarding the three CAS numbers [REDACTED] nor has the registrant responded to the Agency's deficiency letter of November 13, 2008 (Product Chem., Uncleared Inerts, Chemical identification etc..) If I recall correctly, the inert reviewer was Ms Elizabeth Fertich, I will contact her to obtain her review

Raderrio

Linda Hollis

Raderrio: John Redden has agreed to do a Han...

04/08/2009 12:16:06 PM

From: Linda Hollis/DC/USEPA/US
To: wilkins.raderrio@epa.gov
Date: 04/08/2009 12:16 PM
Subject: Catnip

Raderrio: John Redden has agreed to do a Hand to Mouth Assessment for the Catnip products. This should determine how we move forward with the other products provided the inerts are cleared. You will need to do two things and this is to be done immediately.

1. Contact PV Shahs group for the reviewer of the inerts petition and request a copy of the reviews.
2. Bean a copy of that information, our tox review and label to John Redden. He has agreed that you can just give it to him straight. John may need additional information so please provide if he does.

Thirdly, I am unclear to date as to whether or not the supplier has petitioned the Agency for clearance for the other inerts.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

04/10/09
Bill Cutchin
John Redden
speak with John
to set up a meeting

note: as of 4/15/09, Dupont
Chemical has not petitioned
IIAB for clearance of
the three main
inerts. Raderrio



Re: [REDACTED] Approval letter
Elizabeth Fertich to Linda Hollis
Cc: Raderrio Wilkins, Pv Shah, Keri Grinstead, Karen Samek

03/04/2009 05:03 PM

History

This message has been replied to.

Linda,

I looked into your question on the other 3 inert ingredients on your CSF. We received and approved a new nonfood request from [REDACTED] only. I read over Keri Grinstead's letter from 10/28/2008 and based on discussions with her, there are still outstanding inert deficiencies on the Confidential Statement of Formula that have not been addressed [REDACTED] and [REDACTED] remain unapproved inerts and we do not show that any petitions have been received by the Agency.

In addition, as indicated in Keri's letter, we still need full compositional information for [REDACTED] to ensure that there are not other unapproved inerts included in those trade name products. Compositional information needs to be on the manufacturers company letterhead and includes the full product name and the chemical name, CAS No., and %(by wt) in formulation of each component-components must total 100%. This information may be submitted directly to the agency.

Please let me know if you need any more information or have any questions.

Thanks,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch
fertich.elizabeth@epa.gov
703-347-8560

Linda Hollis

Elizabeth. Raderrio Wilkins (the regulatory pers...

03/04/2009 03:05:31 PM

From: Linda Hollis/DC/USEPA/US
To: Elizabeth Fertich/DC/USEPA/US@EPA, Pv Shah/DC/USEPA/US@EPA
Cc: Karen Samek/DC/USEPA/US@EPA
Date: 03/04/2009 03:05 PM
Subject: Re: [REDACTED] Approval letter

Elizabeth: Raderrio Wilkins (the regulatory person assigned to this case) has informed me that there are 3 more [REDACTED] that are not approved. Does your request contain a petition for only one. Raderrio has a letter from Keri Grinstead which states what needs to be petitioned and therefore cleared. I really need to get this clarified. Do you need a copy of the letter to check?

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard

2777 S. Crystal Drive
Arlington, VA 22207
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>


Elizabeth Fertich

Hi Linda, Here is the copy of the approval letter ..

03/04/2009 02:01:19 PM



Re: Fw: [REDACTED]
Raderrio Wilkins to: Linda Hollis
Cc: andersen.janet

Approval letter 
03/04/2009 02:57 PM

Linda,

Please resend the approval letter for [REDACTED] I can open the attachment. In addition, the products (EPA File Symbols 71654-EG and ER) contains three other chemicals [REDACTED] [REDACTED] not approved for use as inert ingredients in pesticides. To my knowledge, I am not aware of IAB being in receipt of any new inert ingredient requests, petitions or correspondences regarding the three CAS numbers nor has the registrant responded to the Agency's deficiency letter of November 13, 2008.

Sincerely,
Raderrio

Linda Hollis

The [REDACTED] contained in th... 03/04/2009 02:09:29 PM

From: Linda Hollis/DC/USEPA/US
To: wilkins.raderrio@epa.gov
Cc: andersen.janet@epa.gov
Date: 03/04/2009 02:09 PM
Subject: Fw: [REDACTED] Approval letter

The [REDACTED] contained in the Catnip formulations have been cleared by the inerts branch for non food use. See letter below. The registrant successfully petitioned the Agency. We should be well on our way with completion for the remaining products.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
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(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

— Forwarded by Linda Hollis/DC/USEPA/US on 03/04/2009 02:07 PM —

From: Elizabeth Fertich/DC/USEPA/US
To: Linda Hollis/DC/USEPA/US@EPA
Cc: Pv Shah/DC/USEPA/US@EPA, Karen Samek/DC/USEPA/US@EPA
Date: 03/04/2009 02:01 PM
Subject: [REDACTED] Approval letter

Inert ingredient information may be entitled to confidential treatment


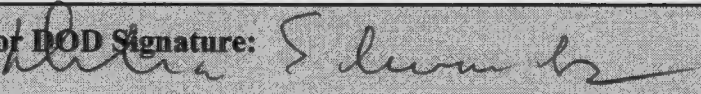
Hi Linda,

Here is the copy of the approval letter you requested when speaking to Karen Samek. If you need anything else please let me know.

[attachment "Acceptance letter for [REDACTED].pdf" deleted by Linda Hollis/DC/USEPA/US]

Thanks,
Beth

Elizabeth Fertich
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch
fertich.elizabeth@epa.gov
703-347-8560

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372756	Registration#: 71654-EG	Petition #: N/A
Fee Category: B60 (PRIA 1)	PRIA Decision Time Frame: 12 months	
Submitted by: Raderrio Wilkins	Branch: BPB	Date: November 26, 2008
Company: Dupont Chemical Solution		
Original Due Date: Nov. 17, 2007	Proposed New Due Date: July 31, 2009	
Previous Negotiated Due Dates: 11/17/07, 5/30/08, and 11/30/08		
Is the "Fix" in-house? No	If not, date "Fix" expected: February 28, 2009	
Issue (describe in detail): In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (change in four inerts or submit inerts substantially similar). The Agency received the resubmitted data package in mid-March which partially addressed the Agency's concerns. The product contains four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as requested in the Agency's letter of October 16, 2007. To date, the product chemistry data remain incomplete.		
Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D) Product Chemistry: <u> D </u> Acute Tox: <u> </u> Efficacy: <u> D </u> Labeling: <u> </u> Other (describe): <u> </u>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Mr. Thomas McEntee) is extremely slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.		
"75 Day" Letter sent? <u>10/16/07 and 11/13/08</u> (Date sent) Yes <u> </u> No and reason for none? <u> </u>		
Note: Application was submitted under PRIA 1		
Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to 8 months. The registrant must submit an application for inert clearance to RD, in addition to addressing other deficiencies.		
Registrant notified that this is the last negotiation? <u> X </u> Yes <u> </u> submission was submitted and <u> </u>		
Approve: 	Disapprove:	
If disapproved, action to be taken:		
OD or DOD Signature: 		Date: <u>11/28/08</u>



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>

11/26/2008 12:44 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc

Subject Re: Refined Oil of Nepeta cataria -- Renegotiated PRIA
Action Dates to the calenar year 2009

Ms. Linda Hollis,

This will confirm the negotiated dates are in calenar year 2009 as you have
detailed below.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

11/26/2008 12:07
PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
wilkins.raderrio@epa.gov
Subject
Re: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates

Thank you, but there are some errors. The dates reflect year 2008. The
dates should be the following:

71654-EN December 5, 2008

71654-EL and EU March 31, 2009

71654-EG and ER July 31, 2009 with the understanding that the Agency
may likely to renegotiate again if the the Agency is not in receipt of
all of the missing information, to include submission of the inert
information to the Registration division by February 28, 2009.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

hollis.linda@epa.gov
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(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

11/26/2008 12:00
PM

To
Linda Hollis/DC/USEPA/US@EPA
cc
Raderrio Wilkins/DC/USEPA/US@EPA
Subject
Refined Oil of Nepeta cataria --
Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the need to renegotiate PRIA dates for the following applications for registration.

File Symbol	Product	Date	
71654-EN	Technical	December 5, 2008	(accomodate review of new active ingredient fact sheet)
71654-ER	15% Lotion	July 31, 2008	(acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate)
71654-EG	7% Lotion	July 31, 2008	(same as 71654-EG)
71654-EL	15% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series)
71654-EU	7% Liquid	March 31, 2008	(resolve disconnect on acute toxicolgy series from 71654-EL)
All			(re-review MRID 47362603 - Supplemental Efficacy Explanations; after the fact HSRB upgrades)

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee
302 695 6856
978 335 8055 CELL

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 13 2008

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No.: 71654-EN (TGAI), -EG, -ER,
PRIA Due Date November 30, 2008

Dear Mr. McEntee:

Please refer to my email dated May 28, 2008 and deficiency letter dated April 16, 2008. Your application remains deficient and we can not proceed with reviewing your application for the end use formulations with the inert clearance issue being unresolved. We renegotiated the PriA due dates for your products to reflect a date of November 30, 2008 with the understanding that you would address the "all" of the deficiencies identified in the Agency's letter dated October 16, 2007, along with submitting the materials necessary for the Inerts Branch to review and possibly resolve. BPPD was informed by Karen Angulo and Prakash Shah of the Inerts Branch that you have not submitted the requested information in a formal request or petition to have the inerts reviewed for clearance.

Therefore, your applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

I. CSF

EPA File Symbol 71654-EG (7% Lotion)

a. Provide a complete address and CAS registry number for the component [REDACTED].

b. Please change the CAS No. for [REDACTED] and for [REDACTED].

*follow up letter
to Mr. McEntee
giving a status report
on the products.
(Refer to Linda Hollis
email dated 10/31/08.
R. Delli
also see email dated
9/30/08 sent to Linda
from Rodemir on
status.*

c. Please provide a CAS No. for the active ingredient.

d. [REDACTED]
[REDACTED] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [REDACTED]
[REDACTED]
[REDACTED] on the CSF.

f. Please address the discrepancy of why the content of [REDACTED]
[REDACTED] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [REDACTED]
[REDACTED] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

EPA File Symbol 71654-ER (15% Lotion)

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

II. PRODUCT CHEMISTRY

File Symbol 71654-EG (7% Lotion)

a. Please provide a rationale for the increase in percent weight of [REDACTED] in the 7% lotion when compared to the TGAI.

b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).



File Symbol 71654-ER (15% Lotion)

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

III. PHYSICAL PROPERTIES

File Symbol 71654-EG (7% Lotion)

- a. Please address oxidation/reduction: chemical incompatibility and explodability.
- b. Submit storage stability and corrosion characteristics tests upon their completion.

File Symbol 71654-ER (15% Lotion)

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are ACCEPTABLE.

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to nontarget organisms. EPA will therefore, waive the testing guideline for Tier I non-target toxicity applicable to TGAI.

IV. PRODUCT PERFORMANCE

- a. Please provide detailed discussion on the statistics employed to analyze the data.
- b. Please address the inconsistencies concerning the amount of test material applied to subjects.

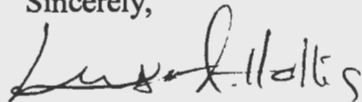
- c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).
- d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of November 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

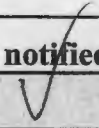
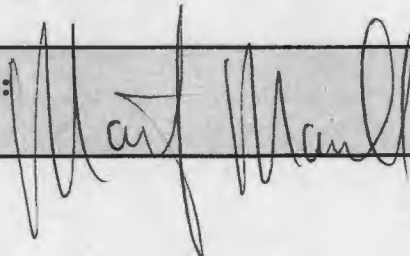
If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of this letter at (703) 308-1259 with your response.

Sincerely,



Linda Hollis., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

**Recommendation of Division Directors
Negotiated Due Dates**

Decision#: 371861, 372756, and 371862		Registration#: 71654-EN, -EG and -ER		Petition #: N/A	
Fee Category: B60			PRIA Decision Time Frame: 6 months		
Submitted by: Raderrio Wilkins			Branch: BPB		Date: November 8, 2007
Company: DuPont Chemical Solution					
Original Due Date: November 21st , 2007			Proposed New Due Date: May 30, 2008		
Previous Negotiated Due Dates: None (this is the company's first renegotiation)					
Is the "Fix" in-house? No				If not, date "Fix" expected: February 2008	
Issue (describe in detail): In a deficiency letter (dated October 16, 2007), the Agency offered DuPont Chemical Solution an opportunity to renegotiate their PRIA Due Date of November 21, 2007 to May 30, 2008 to address Product Chemistry and Performance deficiencies and submit the required Toxicology study.					
Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D) Product Chemistry: <u>D</u> Acute Tox: <u>D</u> Efficacy: <u>D</u> Labeling: <u> </u> Other (describe): <u> </u>					
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Mr. Thomas McEntee) has not responded to the 10/16/07 deficiency letter. On November 8, 2007, however, BPPD received a commitment agreement from Mr. McEntee acting on behalf of his client DuPont Chemical Solution requesting that their PRIA due date be extended to May 30, 2008.					
"75 Day" Letter sent? <u>October 16, 2007</u> (Date sent) Yes <u> </u> No and reason for none?					
Rationale for Proposed Due Date: An extension of the PRIA decision date is equivalent to BPPD PRIA Phase IV-V, plus lag-time for generation and submission of data					
Registrant notified that this is the last negotiation? <u>Yes</u> <u>X</u> Not Applicable					
Approve: 			Disapprove:		
If disapproved, action to be taken:					
OD or DOD Signature: 				Date: 11-13-07	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

November 8, 2008

Dupont Chemical Solution Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

Re: Application for a new Biochemical Pesticide Registration for Refined Oil of *Nepeta cataria*

I Thomas McEntee agree to renegotiate the PRIA Due Dates for the following
A: 71654-EN, EY, ER A. MAY 30, 2008
product(s): B: 71654-EL, EU to B: JUNE 30, 2008 date.

Furthermore, I agree that this renegotiated time frame will include submission of all deficient data to be provided to the Agency AT OR AROUND Feb, 2008 date.

In addition, I understand that should the information be submitted after the agreed upon date of February 2008, an additional renegotiation maybe necessary.

Thomas McEntee
(Signature of Registrant or Consultant)

Nov. 8 2007
(Date)

Information to be resubmitted:

- product chemistry (CSF deficiencies)
- change in 4 inserts (will submit inserts of substantial similarity)
- efficacy → supplemental info regarding description of studies, species etc to be submitted
- Mutagenicity Study to validate or confirm results of originally submitted study, (Point Mutation Assay)
- Refer to def. letter dtd. Oct. 16, 2007, minutes of 11-8-07 meeting & Addendum to def. Hr. dtd. 11-8-07

~~Registration Meeting~~ Nov. 8, 2007

Registration Meeting w/ DuPont Chem

Name

Title

1. Roderick Wilkins	BPPB	Reg. Action Coord.
2. Clara Fuentes	BPPB	Sci. Reviewer
3. Roger Gardner	BPPD/BPP	Branch Senior Scientist
4. KENT CARLSON	BPPD/BPP	SCIENTIST
5. MINAA Hollis (703-308-8733)	BPPD/BPP	Branch chief
6. DAVID HALLAHAN	DuPont	RESEARCH Assoc.
7. Shannon Bullard	DuPont	Project Leader
8. Tom McEntee	DuPont	Product registration manager



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>

11/05/2008 09:31 AM

To Linda Hollis/DC/USEPA/US@EPA

cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: Status of Catnip Pending product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the deficiency letters.

I have been in contact with [REDACTED] after he was able to return to his office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations which you have been handling. I'll endeavor to detail the date at which we expect to submit the information on the inert or have it submitted directly to you.

Thank you for all of your efforts with the applications and successful completion of the technical grade product.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

10/31/2008 09:06
AM

To
Thomas C McEntee/AE/DuPont@DuPont

cc
wilkins.raderrio@epa.gov

Subject
Status of Catnip Pending product
applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The technical product application will be registered by the pria due date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGAI material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the proprietary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to

???

how to proceed with the supplier of this blend. If fact, we do have record of contact with [REDACTED] who has provided us with information, but unfortunately, not what we need. Communication on the part of [REDACTED] did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [REDACTED] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [REDACTED] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer pria. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

October 28, 2008

MEMORANDUM

Subject: Inert Ingredient Review of the proposed Confidential Statements of Formula for 71654-EG (12/5/2006) and 71654-ER (10/19/2006)

From: Keri Grinstead
Inert Ingredient Assessment Branch
Registration Division

To: Raderrio Wilkins
Biopesticides and Pollution Prevention Division

The Inert Ingredient Assessment Branch (IIAB) has reviewed the inert ingredients on the proposed Confidential Statements of Formula for the products listed above. Based on this review, IIAB confirms that the following CAS numbers remain not approved for use as inert ingredients in pesticide products: [REDACTED]

[REDACTED] Any trade name or proprietary blend products containing these CAS numbers are also not approved for use as inert ingredients. Additionally, the CAS number listed for [REDACTED] is not valid and the Agency is lacking full compositional information for the following trade name products: [REDACTED]. Full compositional information for trade name products is necessary for the Agency to verify/review the components for approval.

Some information was received by IIAB for [REDACTED], however, this information was determined to be insufficient for further IIAB review. The submitter was notified that additional information was necessary and, to date, no further response or information has been received regarding this CAS number. Additionally, IIAB has not received any new inert ingredient requests, petitions, or correspondence regarding the other three CAS numbers ([REDACTED]).

Based on this information, the above CAS numbers remain ineligible for use as inert ingredients in pesticide products. For future reference, all inert ingredients on a proposed CSF must be approved for the product's labeled uses prior to the Agency granting a registration.

Inert ingredient information may be entitled to confidential treatment

Information regarding inert ingredients permitted in pesticide products can found on the inerts website at <http://www.epa.gov/opprd001/inerts/lists.html>. Guidance for submitting a new inert ingredient request/petition and/or submitting compositional information can be obtained by emailing IIAB at InertsBranch@epa.gov or calling Keri Grinstead at 703-308-8373.

Please let me know if I can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "Keri Grinstead". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Keri Grinstead (703)308-8373
Inert Ingredient Assessment Branch
Registration Division

Raderrio
Wilkins/DC/USEPA/US
09/30/2008 06:15 PM

To Linda Hollis/DC/USEPA/US@EPA
cc
bcc
Subject The status on the Catnip Products (71654-EG, ER, EU and EL)

Linda,

Per your request, I summarized the status of the Catnip products for your information (details listed below).

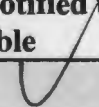
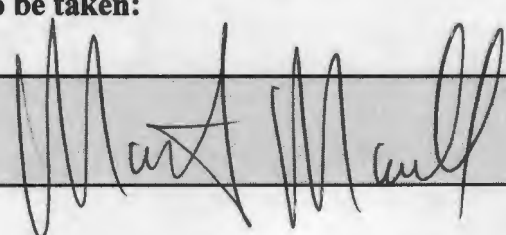
EPA File Symbol 71654-EN (TGAI):

1. The registrant addressed the Product chemistry for the TGAI in MRIDs (47362601 and 47362602).
2. The registrant must submit storage stability and corrosion characteristics tests.
3. The Tier I Toxicity studies have previously been termed **ACCEPTABLE** (Gardner to Wilkins 10/04/07; Wilkins to McEntee 10/16/07). DuPont submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an **ACCEPTABLE** rationale for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.
4. Although product performance data is not required for the registration of the TGAI (Refined oil of *Nepeta cataria*), however DuPont responded to the study deficiencies by submitting a supplement (MRID 47362603) to the previously submitted **UNACCEPTABLE** study. **The supplement satisfactorily addressed the scientific deficiencies present in the original studies, however ethical issues still have not been resolved and may need further review (Classification remains UNACCEPTABLE, but upgradable).**
In particular, ethical questions involve, but are not limited to:
 - 1) The use of employees of Insect Control & Research in mosquito bite-testing,
 - 2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
 - 3) Other issues identified in a previous review (Fuentes to Wilkins 10/04/07).

EPA File Symbol 71654-ER and EG (EPs):

1. Product chemistry and CSF deficiencies for the 7% (71654-EG) and 15% (71654-ER) lotion have not been addressed as requested (Wilkins to McEntee, 10/16/07). I am not in receipt of any resubmission for products **71654-ER, EG, EU or EL.**

Sincerely,
Raderrio

Recommendation of Division Directors Negotiated Due Dates		
Decision#: 372756	Registration#: 71654-EG	Petition #: N/A
Fee Category: B60 (PRIA 1)	PRIA Decision Time Frame: 12 months	
Submitted by: Raderrio Wilkins	Branch: BPB	Date: May 19, 2008
Company: Dupont Chemical Solution		
Original Due Date: Nov. 17, 2007	Proposed New Due Date: November 30, 2008	
Previous Negotiated Due Dates: 5/30/08		
Is the "Fix" in-house? No	If not, date "Fix" expected: 6/13/08	
Issue (describe in detail): In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, species etc.), and Mutagenicity Study (Point Mutag. Assay to validate or confirm results) for products 71654-EN, -ER, -EG, -EU and -EL by the end February 2008 to support the bridging of data. The Agency received the resubmitted data package in mid-March. Furthermore, the product contain four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as outlined in the Agency's letter of October 16, 2007. Failure to submit the missing data by the end of February impacted the new Pria Date of May 30, 2008. To date, the information as resubmitted remains incomplete.		
Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D) Product Chemistry: <u> D </u> Acute Tox: <u> D </u> Efficacy: <u> D </u> Labeling: <u> </u> Other (describe): <u> </u>		
Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Mr. Thomas McEntee) is extremely uncooperative and slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief.		
"75 Day" Letter sent? <u> 10/16/07 </u> (Date sent) Yes <u> </u> No and reason for none?		
Note: Application was submitted under PRIA 1		
Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases II – V, which is equivalent to 6 months. The 180 day extension would allow the registrant time to resolve their formulation problem by change the four inert to a substantially similar chemical or submit an application for inert clearance to RD.		
Registrant notified that this is the last negotiation? <u> X </u> Yes <u> </u> submission was submitted and <u> </u> Not Applicable		
Approve: 	Disapprove:	
If disapproved, action to be taken:		
OD or DOD Signature: 	Date: 5-29-08	

Linda Hollis/DC/USEPA/US

05/28/2008 09:09 PM

To "Thomas C McEntee"

<Thomas.C.McEntee@usa.dupont.com>, Pv

Shah/DC/USEPA/US@EPA, Karen

cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: e-courtesy copy -- formal request to add inert

It has been noted that this is a courtesy copy. The Agency will act on an official copy submitted to the document processing center per my last email to you. Once submitted, the -nerts branch will determine if the information is sufficient to review.

to -----\Sent by EPA Wireless E-Mail Services.

----- Original Message -----

From: Thomas C McEntee [Thomas.C.McEntee@usa.dupont.com]

Sent: 05/28/2008 04:45 PM AST

To: Pv Shah; Karen Angulo

Cc: Linda Hollis; Raderrio Wilkins

Subject: e-courtesy copy -- formal request to add inert

Dr. PV Shah and Ms. Karen Angulo,

The attached file was expressed to IIAB today.

If you have any questions, please feel free to call or e-mail.

(See attached file: 20080528 BINDER Signed Cover PV Shah 7% and 15% LOTIONS
[REDACTED].pdf)

Tom McEntee

302 695 6856

978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

05/28/2008 01:31 PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Wilkins.Raderrio@epamail.epa.gov,
Shah.Pv@epamail.epa.gov,
andersen.janet@epa.gov

Subject
Re: Resubmission of Information
71654 - ER and EG

Inert ingredient information may be entitled to confidential treatment

Dear Mr. McEntee:

Your application remains to be deficient and we can not proceed with review of the applications for the end use formulations with the inert clearance issue being unresolved. We renegotiated the PRIA due date for your product to reflect a date of November 2008 with the understanding that in doing so, the materials necessary for the Inerts Branch to review and possibly resolve the inerts issue were in house and were in the queue. I have learned as of yesterday in a conversation with both Karen Angulo and Prakashcha Shah (Pv Shah) of the Inerts Branch that you have not submitted a formal request or petition to have the inert reviewed for clearance. You indicated in an email to Karen Angulo information that you intended to present at the presubmission meeting scheduled for April 23, 2008. Unfortunately, you did not show up for the meeting and the Inerts Branch has to date not received any formal submission from you. It is also unclear from your email to Karen Angulo whether or not your interest lies in clearance for a food or non food use. At any rate, the email to K. Angulo, does not suffice or negate the need for you to make a formal submission. The information submitted in the email, per the Inerts group is not sufficient for them to consider, further, your request, per the Inerts Group is not currently on their schedule. In order for the Inerts Group to review your request, they will need an official/formal request/petition. The Inerts group will not add you to their schedule until your and successfully completed the following steps:

- 1) submit a formal submission (non-food) and or petition (food) to IIAB, and;

- 2) It is determined by the Inerts Group that it is sufficient to work on. When this determination is made, the Inerts group may be able to give you an estimated completion timeframe.

This missing information will affect your new due date as the time frame was calculated based on the understanding that your information had been officially submitted and was being reviewed. As a result, you will only have 75 days from the date of this email (August 11, 2008) to officially submit the above information through the EPA Document Processing Center. Failure to submit the information by August 11, 2008 will result in a can not grant for the end use applications.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee

<Thomas.C.McEnte
e@usa.dupont.com
>

05/28/2008 10:55
AM

To
Linda Hollis/DC/USEPA/US@EPA,
Raderrio Wilkins/DC/USEPA/US@EPA
cc

Subject
Re: Resubmission of Information
71654 - ER and EG

(See attached file: 20080528 Resend cover letter inert Lotion
substitutue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA
DER
9/19/07. Following the November 20067 meeting with you, the formulas
were
revised to substitute chemically and functionally equivelant ingredients
which are on EPA's list with the exception of one inert. This inert is
the
subject of the submission to IIRB on April 30, 2008.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

To
05/13/2008 11:53
McEntee/AE/DuPont@DuPont,
AM

Thomas C
Wilkins.Raderrio@epamail.epa.gov

cc

Subject

Re: Resubmission of Information
71654-EN, ER, EG and EL

I believe that your submission was submitted late in addition to the fact that there were deficiencies outlined in our letter which you have not addresses in your resubmission. I am unclear as to your involvement with the inerts group for clearance however the information as resubmitted thus far remain deficient. You may either renegotiate or we will elect to issue a can not grant. Alternatively, you can withdraw.

-----Original Message-----

From: Thomas C McEntee
To: Raderrio Wilkins
To: Linda Hollis
Sent: May 13, 2008 11:06 AM
Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

Thank you for your telephone call. I am still trying to confirm that IIRB has received the documents on the unlisted inert from our supplier, which affect the review cycle for the end-use formulated lotions.

Returning to the previous negotiated date for the Nepeta catariaTechnical and Manufacturing Use Product (71654- EN) [EPA letter of Nov. 8, 2007], the PRIA date was May 30, 2008. We met the target date of February 2008 for re-submission. Extension of the PRIA date out to November for the technical registration does not seem justified.

Please let me know of any developments which are a basis for your suggestion of a November date for the technical registration.

Thank you for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM

Thomas C
McEntee/AE/DuPont

To

05/06/2008 05:54

Hollis.Linda@epamail.epa.gov@DUPONT

PM

_MHUB

cc

wilkins.raderrio@epa.gov

Subject

Re: Fw: Resubmission of
Information 71654-EN, ER, EG and EL
(Document link: Thomas C McEntee)

Ms. Linda Hollis,

Thank you for your e-mails. I will be completing the submissions on the end-use formulas this week.

This is to confirm that I will request a renegotiated action date for the applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta cataria Technical and Manufacturing Use Product"
EPA

File Symbol 71654-EN

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU

"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007

EPA letter of August 29, 2007

EPA letter of April 16, 2008

EPA-Dupont November 8, 2007 meeting

(See attached file: [REDACTED].pd

-----Original Message Truncated-----

to -----\Sent by EPA Wireless E-Mail Services.

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http://www.DuPont.com/corp/email_disclaimer.html

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf){attachment "20080528 Resend cover letter inert Lotion substitue.pdf" deleted by Thomas C McEntee/AE/DuPont]

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http://www.DuPont.com/corp/email_disclaimer.html



Karen Angulo/DC/USEPA/US
05/27/2008 03:43 PM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA, Pv
Shah/DC/USEPA/US@EPA
bcc
Subject Fw: confirmation of receipt and pre-submission conference
"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol
71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA
File Symbol 71654-EG

Hello Linda,

Here is the email from Tom McEntee. It appears he is interested in food and non-food approval, but this is not clear. This is what he was going to explain during the pre-submission meeting in April, but he canceled that meeting. The next thing we received from him was the email below. We need him to submit more than what he has and submit a formal request/petition. What he has sent is not sufficient for us to consider. His request is not currently on our schedule, and will not be added to our schedule until he 1) submits his formal submission (non-food) and or petition (food) to IIAB, and 2) we determine it is sufficient to work on. At that time we may be able to give you an estimated completion timeframe.

Thanks,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

----- Forwarded by Karen Angulo/DC/USEPA/US on 05/27/2008 03:28 PM -----



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>
05/09/2008 12:57 PM

To Karen Angulo/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
Subject confirmation of receipt and pre-submission conference
"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol
71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA
File Symbol 71654-EG

(See attached file: [REDACTED] Letter of Authorization [REDACTED].pdf)

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

Hello Karen,

Can you let me know if it can be confirmed that a re-qualification has been initiated relative to the product mentioned in the above letter? Can we discuss by phone or schedule a conference to get an estimate of the time required for your branch to complete the risk assessment? Do you need any other information to link the submission to our application?

BPPD has indicated the need to allow time for your assessment, so in order to negotiate a new PRIA target date, I would like to get your estimates.

I am still trying to finalize access to confidential information for other inert ingredients for a pre-application consultation. These different ingredients would be required for completely different technology than the immediate situation with the resubmissions.

Thank you for your assistance to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epamail.epa.gov

04/15/2008 12:37 PM

Thomas C McEntee/AE/DuPont@DuPont
To
cc

Shah.Pv@epamail.epa.gov,
Leifer.Kerry@epamail.epa.gov,
Samek.Karen@epamail.epa.gov,
Grinstead.Keri@epamail.epa.gov,
Martin.Kathleen@epamail.epa.gov

Subject
Re: Thank you and request for
Pre-Submission Conference.

Hello

I scheduled your pre-submission meeting for next Wednesday, April 23rd, from 1 - 2 pm. Schedules are tight and that is the best day/time of the days you proposed. If this is not convenient for you, lets try for the following week. Would you like to do this via conference call?

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

04/09/2008 05:25
PM

To
Karen Angulo/DC/USEPA/US@EPA
cc
Subject
Re: Thank you and request for
Pre-Submission Conference.

Karen,

Thank you for the prompt reply,

I will be in the area on April 16 and 17th. I could meet on Wed. the 16th after 2:00 or break away from the ACC-biocides Panel meeting on Thursday 17th.

Alternatively, April 22/Tuesday or April 23/Wednesday.

Thanks for your consideration.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epamail.epa.gov

To
04/09/2008 04:49
PM
cc
Thomas C McEntee/AE/DuPont@DuPont
leifer.kerry@epa.gov,
shah.pv@epa.gov
Subject
Re: Thank you and request for
Pre-Submission Conference.

Hello,

We are happy to schedule a pre-submission meeting for you. It would be helpful if you let me know several dates that you are interested in.

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

04/09/2008 01:15
PM

Pv Shah/DC/USEPA/US@EPA, Karen
Angulo/DC/USEPA/US@EPA, Kerry
Leifer/DC/USEPA/US@EPA

To

cc

Subject

Thank you and request for
Pre-Submission Conference.

P.V. , Karen and Kerry,

Thank you and your staffs for the very illuminating meeting yesterday, The progress you are making will be a huge help in or efforts to develop and register newer technology. The uncertainty around inerts has been a major disincentive to investing in safer, more sustainable formulas and product forms.

This e-mail is also a request for a pre-submission meeting to discuss requirements for the following three projects with inert issues:

1. Refined Oil of Nepeta cataria Insect Repellent Lotion - BPPD

(See attached file: Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf)

The proposed lotion contained several ingredients that are common in cosmetics, but apparently not in currently registered insect repellents or other formulas.. I am still refining a re-submission to address the inert issues.

2. Self-Sanitizing Antimicrobial coating for non-food contact surfaces in food preparation and service areas.

(See attached file: cloroxpcol_final.pdf)

http://www.epa.gov/oppad001/cloroxpcol_final.pdf

We are in an advanced state of development of a formula to register for the above claim. The formula requires 4 ingredients that are presently not listed.

3. Enzymatically activated in-situ Active Ingredient

We are at a mid-point development of a new antimicrobial formulation which produces the active ingredient in-situ at the point of use. The product will be used as a hard surface disinfectant. It may also be extended to laundry sanitizer and food contact use. Food contact use would be expected to require tolerance formality. It would be very valuable understand your view of risk assessment of a new enzyme. (The active ingredient is allowed at 40 CFR 180.940 without limitation as to origin).

Please let me know your availability to meet so that we can move these three projects forward.

Thank you for your assistance.

Tom McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
302 695 6856
978 335 8055 CELL

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

[attachment "Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf"
deleted by Karen Angulo/DC/USEPA/US] [attachment "cloroxpcol_final.pdf"
deleted by Karen Angulo/DC/USEPA/US]

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

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Letter of Authorization.pdf



DuPont Chemical Solutions Enterprise

May 14, 2008

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Renegotiated PRIA Due Dates

"Refined Oil of *Nepeta cataria* Technical; EPA File Symbol 71654-EN
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG
"Refined Oil of *Nepeta cataria*" 7% Liquid; EPA File Symbol 71654-EU
"Refined Oil of *Nepeta cataria*" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007
EPA letter of August 29, 2007
EPA letter of April 16, 2008
EPA-Dupont November 8, 2007 meeting

DuPont is accepting a renegotiated PRIA due date of November 30, 2008 which allows six months for EPA review of all of the items.

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas C. McEntee", written over a horizontal line.

Thomas C. McEntee

Product Registration Manager

Thomas.C.McEntee@usa.dupont.com

(302) 695 6856

Inert ingredient information may be entitled to confidential treatment *Product ingredient source information may be entitled to confidential treatment*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

APR 16 2008

Re: Application for a Biopesticide Registration
Refine Oil of *Nepeta cataria*
EPA File Symbol: 71654-ER, EG, EN, EL and EU

Dear Mr. McEntee:

Please refer to my email dated March 13, 2008. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were not cleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a PRIA action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so. We will therefore need to know, with some urgency how you will proceed. You have the following options:

(A). Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.

(B). Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.

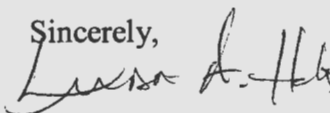
(C). Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of May 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the five products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately from the date of this letter at (703) 308-1259 with your response.

Sincerely,



Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)

Linda Hollis/DC/USEPA/US
03/13/2008 11:51 AM

To Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
cc Driss Benmhend/DC/USEPA/US@EPA, Raderrio
Wilkins/DC/USEPA/US@EPA
bcc
Subject Resubmission of Information 71654-EN, ER, EG and EL

Dear Mr. McEntee:

I understand that you have been in conversation with Raderrio Wilkins of my staff regarding the fact that data that was to be submitted (in agreement between Dupont and the Agency) by the end of February to address deficiencies in the above product has only arrived within the past week. It should be noted that there were 86-5 deficiencies that you have responded to and at this time do not know if the data are 86-5 compliant. This delay in submission prompted our need to renegotiate the due date for all of the above products because too much time has now lapsed for EPA to review any materials in support of the above submissions and make a regulatory decision by the due dates of May 30th and June 30th respectively. Our recommendation initially was for you to renegotiate the due dates for all of the above products to be in line with the due date of your -EU product of August 30, 2008.

Mr. Wilkins has informed me that there are additional outstanding issues which have not been addressed in this most recent resubmission. Our letter to you dated October 16, 2007 which referenced pending products: 71654- EG and ER, EL and EU, stated that your formulations contained inert ingredients that were uncleared. Our policy is such that any inert ingredient contained in a formulation must be cleared prior to the issuance of registration. Under PRIA 2, inert clearance for the Biopesticides and Pollution Prevention is not considered a pria action. You may submit the information in support of inert clearance to the Agency in a separate application. The Registration Division is responsible for clearing all inert ingredients. BPPD will however, consult with the Registration Division on inerts subject to be used in formulation for BPPD products. Nonetheless, this is a function that must be done before your application can even be considered for regulatory review. Therefore, you will need to make some decisions. While there is no statutory timeframe attached to clearance of inert ingredients, I understand that the process can be at the minimum six months, but this will depend on the workload of those involved. You have made reference to working with Kerry Leifer of the Agency. While Mr. Leifer does work in the branch responsible for clearance of inerts, you must make an application to the Agency to do so.


We will therefore need to know, with some urgency how you will proceed. You have the following options.

- A. Renegotiate the due date for all of the above actions and consider the time that it will take for you to make a separate application to the Agency for inert clearance and have the Agency to conduct review. It is important to note that you can negotiate the due date for a time frame that you feel is feasible, regardless of the length.
- B. Withdraw the applications until such time when you have addressed the deficiencies and have all of the data to submit.
- C. Reformulate the product so that all inert ingredients have been cleared. Should you elect this method, you will run the risk of having to withdraw the pending products given that we have already conducted primary reviews and the fact that the formulations may not be substantially similar.

Please respond to Mr. Wilkins in a timely fashion.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division

Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

 Driss
Benmhend/DC/USEPA/US
03/12/2008 09:04 AM

To thomas.c.mcentee@usa.dupont.com
cc Raderrio Wilkins/DC/USEPA/US@EPA, Linda
Hollis/DC/USEPA/US@EPA
bcc
Subject Resubmission 86-5 Failure

Dear Mr. McEntee:

The attached file is in reference to the above registration. Please call me if you have any questions or a problem with the pdf. file.

Thank you,



Dupont.86.5.pdf DuPont.86.5 Failure.doc

Driss Benmhend

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

The United States Environmental Protection Agency

1200 Pennsylvania Avenue. N.W.

Washington, DC 20460

(703) 308-9525

Benmhend.driss@epa.gov

www.epa.gov/oppppd1/biopesticides/



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 11, 2008

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 04-MAR-08. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

* FIFRA Section 10(d)(1) only provides for confidentiality of information which: (A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, or (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide... Since your claim covers information entirely outside this narrow range of subject matter, it cannot be accepted.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Thomas C. McEntee
Product Registration manager
DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

RE: **Refined Oil of *Nepeta cataria* Technical and Manufacturing Use Product**
EPA File Symbol: 71654-EN, ER, EG
Application dated: 02/28/08
Notification of Non-compliance with Pesticide Registration Notice 86-5

Email sent date: 03/12/08
Email address: Thomas.c.McEntee@usa.dupont.com

Dear Mr. McEntee:

The Biopesticides and Pollution Prevention Division (BPPD) have received your submission to register the subject product. All or some of the data were rejected by our Document Processing Unit because they were not submitted as directed in PR Notice 86-5 and should be reformatted and resubmitted to the Document Processing Unit. A copy of PR Notice 86-5 can be found at our website at: http://www.epa.gov/opppmsd1/PR_Notices/pr86-5.html should you need assistance in making the necessary changes.

If you still want to register this product, the application will be kept open for a period of 75 days to give you an opportunity to respond to this memorandum. If you find that you need more time you must request an extension for a reasonable stated period of time. Extension requests must be made immediately to me at (703) 308-8713.

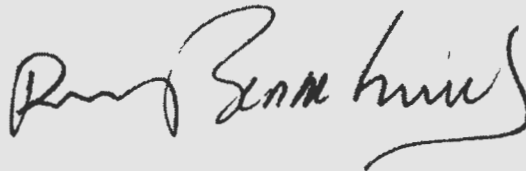
If you do not comply with this procedure by not responding to this letter or requesting an extension of time to resubmit the information, the Agency may administratively withdraw your application from further consideration under the provisions of PR Notice 75-4 of August 27, 1975. Once this is done, you will have to submit completely new application should you wish to pursue the registration of your product after the application has been withdrawn.

The changes and/or corrections required by you are outlined in the attached EPA Transmittal Letter. You must contact me by telephone at the number above or by email at benmhend.dirss@epa.gov and indicate that you will submit the corrected pages via facsimile to **(703) 305-0118**. Once you have faxed the corrected pages, please follow up with an email to me indicating that you have done so.

If the changes are excessive, you may wish to fed-ex or courier the documents to our offices or contact me to arrange to come in to our offices to make the necessary changes. Once all changes have been made, your submission will be forwarded to our Document Processing Unit for PR Notice 86-5 Screening.

Should you have additional questions regarding this matter, please feel free to contact Driss Benmhend, Acting Team Leader for Biochemical Pesticides Branch at (703) 308-9525 or by email benmhend.driss@epa.gov.


Sincerely,

A handwritten signature in dark ink, appearing to read "Driss Benmhend", with a stylized, flowing script.

Driss Benmhend
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

Enclosure

Raderrio
Wilkins/DC/USEPA/US
03/11/2008 03:24 PM

To Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
cc Linda Hollis/DC/USEPA/US@EPA, Driss
Benmhend/DC/USEPA/US@EPA
bcc
Subject Refine Oil of Nepeta cataria EPA File Symbol
71654-ER,EG,EN, EL, and EU - Ref: Nov. 8, 2007 Meeting


Dear Mr. McEntee,

Per the Agency's email of February 21, 2008, informing Dupont Chemicals that you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results) for products 71654-EN, ER, EG and EL by the end February 2008. On February 25, 2008, BPPD received a response to our e-mail notifying the Agency that the requested data would be Fed Ex'ed on Thursday 28, 2008. To date, the Agency is not in receipt of your data package.

As previously mentioned, failure to submit the missing data by the end of February 2008 would impact the new Pria Dates of May 30, 2008 and June 30, 2008 (the renegotiated PRIA Due Date was contingent on the resubmission of 2/08). Should the data referenced above be received after the agreed date of February 2008, you were informed that an additional renegotiation will be necessary. Unfortunately there is not enough time remaining before the PRIA decision date of May 30, 2008 and June 30, 2008 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision..

Therefore, you may renegotiate the due date, or withdraw the application and resubmit when you have all the information or the Agency will issue a can not grant letter under PRIA on or about May 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately at (703) 308-1259 with your response.

Sincerely,
Raderrio Wilkins

Thomas C McEntee <Thomas.C.McEntee@usa.dupont.com>



Thomas C McEntee



<Thomas.C.McEntee@usa.d
upont.com>

02/25/2008 09:57 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

Subject Re: Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting

Mr. Raderrio Wilkins,

I expect to Fed Ex the data on Thursday Feb. 28 for arrival Friday Feb. 29th.

Thank you for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

Wilkins.Raderrio@
epamail.epa.gov

02/21/2008 09:58
AM

To
Thomas C McEntee/AE/DuPont@DuPont
cc

Hollis.Linda@epamail.epa.gov,
Benmhend.Driss@epamail.epa.gov,
Gardner.Roger@epamail.epa.gov,
Carlson.Kent@epamail.epa.gov,
Fuentes.Clara@epamail.epa.gov,
Wilkins.Raderrio@epamail.epa.gov
Subject
Refine Oil of Nepeta cataria - Ref:
Nov. 8, 2007 Meeting

Dear Mr. McEntee,

Per our agreement of November 8, 2007, you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results) for products 71654-EN, ER and EG by the end February 2008. To date, the Agency is not in receipt of this data. Failure to submit the missing data by the end of February will impact the new Pria Date of May 30, 2008. Should the data referenced above be submitted after the agreed date of February 2008, an additional renegotiation will be necessary. In addition, the FR announcing receipt of this new active ingredient is scheduled to be published March 2008.

Sincerely,
Raderrio Wilkins
(703) 308-1259

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>

02/25/2008 09:57 AM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc

bcc

Subject Re: Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting

History:

This message has been forwarded.

Mr. Raderio Wilkins,

I expect to Fed Ex the data on Thursday Feb. 28 for arrival Friday Feb. 29th.

Thank you for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

Wilkins.Raderrio@
epamail.epa.gov

02/21/2008 09:58
AM

To Thomas C McEntee/AE/DuPont@DuPont
cc

Hollis.Linda@epamail.epa.gov,
Benmhend.Driss@epamail.epa.gov,
Gardner.Roger@epamail.epa.gov,
Carlson.Kent@epamail.epa.gov,
Fuentes.Clara@epamail.epa.gov,
Wilkins.Raderrio@epamail.epa.gov
Subject
Refine Oil of Nepeta cataria - Ref:
Nov. 8, 2007 Meeting

Dear Mr. McEntee,

Per our agreement of November 8, 2007, you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results) for products 71654-EN, ER and EG by the end February 2008. To date, the Agency is not in receipt of this data. Failure to submit the missing data by the end of February will impact the new Prida Date of May 30, 2008. Should the data referenced above be submitted after the agreed date of February 2008, an additional renegotiation will be necessary. In addition, the FR

announcing receipt of this new active ingredient is scheduled to be published March 2008.

Sincerely,
Raderrio Wilkins
(703) 308-1259

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

http://www.DuPont.com/corp/email_disclaimer.html

Raderrio
Wilkins/DC/USEPA/US
02/21/2008 09:58 AM

To Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
cc Linda Hollis/DC/USEPA/US@EPA, Driss
Benmhend/DC/USEPA/US@EPA, Roger
Gardner/DC/USEPA/US@EPA, Kent
bcc

Subject Refine Oil of Nepeta cataria - Ref: Nov. 8, 2007 Meeting 

Dear Mr. McEntee,

Per our agreement of November 8, 2007, you were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, spices etc.), and Mutagenicity Study (Point mutag. Assay to validate or confirm results) for products 71654-EN, ER and EG by the end February 2008. To date, the Agency is not in receipt of this data. Failure to submit the missing data by the end of February will impact the new Pria Date of May 30, 2008. Should the data referenced above be submitted after the agreed date of February 2008, an additional renegotiation will be necessary. In addition, the FR announcing receipt of this new active ingredient is scheduled to be published March 2008.

Sincerely,
Raderrio Wilkins
(703) 308-1259



**Biopesticides and
Pollution
Prevention
Division**

FAX

October 22, 2007

TO: Mr. McEntee
Dupont
302-695-6856
302-6951579 (fax)

FROM: Raderrio Wilkins
US EPA Office of Pesticide Programs
Biopesticides & Pollution Prevention Division (7511P)
1200 Pennsylvania Ave NW, Washington, DC 20460
703-308-1259 Fax 703-305-0118
Wilkins.raderrio@epa.gov

RE: AMVAC AZA 1.2% ME (EPA File Symbol 5481-LGL)

MESSAGE: Please call to confirm receiving this fax. Thanks in advance for your cooperation.



Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
10/17/2007 04:08 PM

To Raderrio Wilkins/DC/USEPA/US@EPA
cc
bcc
Subject Re: Refined Oil of Nepeta cataria FAX # 302 695 1579

Mr. Raderrio Wilkins,

This is to confirm that I understand that the fax machine is not confidential and that you cannot guarantee the confidentiality of any letter that is transmitted by facsimile machine.

I will stand by the machine with fax number 302 695 1579, if you will e-mail or call when you are about to transmit.

Thank you for your assistance.

Tom McEntee
302 695 6856
978 335 8055 CELL

Wilkins.Raderrio@
epamail.epa.gov

10/17/2007 03:46
PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Hollis.Linda@epamail.epa.gov
Subject
Re: Refined Oil of Nepeta cataria

Dear Mr. McEntee :

The reviews for 71654-EG,ER and EN (Refined Oil of Nepeta cataria) submissions have been completed. You requested have the letters faxed to you, but they contain confidential business information (CBI). Since there is CBI, the Agency cannot fax the reviews/letters without a note from you indicating that you are aware that the facsimile machine is not confidential and that the Agency cannot guarantee confidentiality if you wish that the reviews/letters are faxed to you.

If you wish to have these faxed then respond via email that you understand that the Agency cannot guaranteed confidentiality and that you still want to have the reviews/letters faxed anyway. Please also include the fax number where you will be waiting for the fax. I will email you when I am going to send the fax. The signed originals were mailed on October 16, 2007.

Furthermore, please keep in mind that any response regarding these reviews/letters must be sent to the Agency, in writing, though the "Front-End Processing Desk."

Regards,
Raderrio Wilkins
Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
USEPA

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

OCT 16 2007

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No. 71654-EN (100%), 71654-EG (7% Lotion), 71654-ER (15% Lotion)
Your submission of November 30, 2006 and resubmissions of December 19, 2006, December 28, 2006 and January 5, 2007.

Dear Mr. McEntee:

The applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and are not acceptable at this time. The Human Health Studies, however are acceptable and satisfy the tier 1 biochemical data requirements for the TGAI and End-Use products. The Product Chemistry and Product Performance data are **not acceptable** for the following reason(s):

I. CSF

EPA File Symbol 71654-EN (TGAI):

- a. Submit s CAS Registry numbers for all ingredients on the CSF. The must be placed after the component descriptor.
- b. All impurities potentially present at >0.1% must be identified individually on the CSF (ie. [REDACTED], etc?) and have upper certified limits calculated.
- c. The information on the top row of the CSF where refined oil of *Nepeta cataria* is identified as "active technical grade" should be deleted.
- d. The parentheses around the amounts of the remaining ingredients provided in column 13b of the CSF must be deleted.

- e. The identity of the active ingredients given on the CSF and the product label must be made consistent.
- f. The certified limits are in excess of what is recommended in 40CFR 158.175(b)(2) and ranges determined in preliminary analyses. Please base the certified limits on that presented in the 40 CFR or provide justification for deviations. EPA would like to note that [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] EPA considers this range satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- g. The lower certified limits for impurities, un-reacted starting materials, etc. must be deleted.
- h. The proposed Upper certified limit for [REDACTED] should be revised to reflect the upper part of the range described in preliminary analyses [REDACTED] EPA considers this satisfactory for regulatory purposes because the component is undetectable in the final EP products.
- i. The proposed upper certified limit for [REDACTED]
[REDACTED]
[REDACTED] EPA considers these upper limits to be satisfactory, considering the variation present in source material supply, source material composition, the negligible amount of these components in EP products, [REDACTED]
[REDACTED] and the anticipation that no additional toxicity (other than that already associated with dihydronepetalactone) will be associated with these components.
- j. Following the addition of other ingredients to the CSF, the please ensure that the percent (%) by weight totals = 100%.
- k. Please complete blocks #5. and #6. on the CSF.

EPA File Symbol 71654-EG (7% Lotion)

- a. Provide a complete address and CAS registry number for the component [REDACTED].
- b. Please change the CAS No. for [REDACTED] and for [REDACTED]

c. Please provide a CAS No. for the active ingredient.

d. [REDACTED]
[REDACTED] are not on the most recent on-line inert ingredients list (August 2004). Please provide alternate components that are on the EPA inert ingredients list or provide information to the inert ingredients branch (IIAB) for listing these (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).

e. Please provide the chemical identities for [REDACTED]
[REDACTED] [REDACTED] [REDACTED] on the CSF.

f. Please address the discrepancy of why the content of [REDACTED]
[REDACTED] given on the CSF does not match the content given in MRID 47003301.

g. Please address the discrepancy of why the supplier for [REDACTED]
[REDACTED] given on the CSF does not match the supplier given in MRID 47003301.

h. Please complete blocks 5. and 6. of the CSF.

EPA File Symbol 71654-ER (15% Lotion)

a. The same conditions and concerns reported for the 7% lotion (above) apply for the 15% lotion.

II. PRODUCT CHEMISTRY

File Symbol 71654-EG (7% Lotion)

a. Please provide a rationale for the increase in percent weight of [REDACTED] in the 7% lotion when compared to the TGAI.

b. Submit MSDSs or specification sheets for the all beginning materials, including those present as components in the mixtures.

c. Submit quality control procedures for the formulation process.

d. Please address the observation that extended storage at ambient conditions (25°C and 60% RH) results in the degradation of dihydronepetalactone and other components.

e. Please submit information regarding the following inert ingredients (below) that are not on the most recent EPA inert ingredients list (August 2004).

BPPD recommends that the EPA inert ingredients branch (IIAB) be contacted for more information (contact in IIAB - Kerry Leifer, leifer.kerry@epa.gov).



File Symbol 71654-ER (15% Lotion)

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

III. PHYSICAL PROPERTIES

EPA File Symbol 71654-EN (TGAI):

- a. Please address explosability.
- b. Please submit storage stability and corrosion characteristics tests.
- c. Please address stability in the presence of different temperatures and metals by discussing the relative impacts that packaging and storage will have on the stability of the product.
- d. Please provide a method for the determination of density.

File Symbol 71654-EG (7% Lotion)

- a. Please address oxidation/reduction: chemical incompatibility and explosability.
- b. Submit storage stability and corrosion characteristics tests upon their completion.

File Symbol 71654-ER (15% Lotion)

- a. The same deficiencies outlined for the 7% lotion (above) apply for the 15% lotion.

2. Tier I Toxicity studies are ACCEPTABLE.

3. Tier I Non-Target studies have not been submitted by the registrant. EPA expects that the use pattern of this product as an insect repellent will preclude significant adverse exposure to

nontarget organisms. EPA will therefore, waive the testing guideline for Tier I non-target toxicity applicable to TGAI.

IV. PRODUCT PERFORMANCE

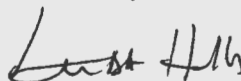
- a. Please provide detailed discussion on the statistics employed to analyze the data.
- b. Please address the inconsistencies concerning the amount of test material applied to subjects.
- c. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken for 1. This information regarding landing rates must be noted in the results table (Appendix IV).
- d. The test sites were not monitored for incidences of mosquito-borne disease prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, there may not be enough time remaining before the PRIA decision date of November 21, 2007 for you to submit the information requested above and for BPPD to complete the review and make a regulatory decision. While these are the major deficiencies that are associated with your application, BPPD is still reviewing other portions of your package.

Therefore, you may renegotiate the due dates for the three products above, or withdraw the application and resubmit when you have all the information or the Agency will issue a cannot grant letter under PRIA on or about November 21, 2006. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately or within five (5) days from the date of this letter at (703) 308-1259 with your response.

Sincerely,



Linda Hollis., Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: October 10, 2007

SUBJECT: Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of *Nepeta cataria* (TGAI), and two lotion end-use products.

Decision Nos.: 371861, 372756, 371862

DP Nos.: 338556, 339493, 339547

EPA File Symbol: 71654-EN (TGAI), 71654-EG
(7% a.i.), 71654-ER (15% a.i.)

PC Code: 004801

MRID Nos.: 469773-01 through -06;
469774-01 through -14, -20 & -22;
470031-02 & -05; 470156-01 & -02

FROM: Roger Gardner, Senior Scientist /s/
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

~~***** CONTAINS CONFIDENTIAL BUSINESS INFORMATION *****~~

ACTION REQUESTED: Review of scientific information submitted by E.I. du Pont de Nemours and Company to support registration of Refined Oil of *Nepeta cataria* (71654-EN) as a dermally applied insect repellent in a 7% Lotion (71654-EG) a 15% Lotion (71654-ER).

RECOMMENDATIONS AND CONCLUSIONS

There are adequate data for conducting a risk assessment that supports registration of the insect repellent Refined Oil of *Nepeta casaria* and the 7% and 15% lotion products. Specific conclusions and recommendations are summarized as follows:

1. The active ingredient is classified into Toxicity Category III for oral toxicity and primary eye irritation and Toxicity Category IV for dermal, inhalation and skin irritation. It is not a skin sensitizer.
2. The lotion formulations containing 7 and 15% active ingredient are classified into Toxicity Category IV for oral and dermal toxicity as well as eye and skin irritation and they are not skin sensitizers.
 - a. The acute inhalation study for the 15% lotion was waived on the basis of the lack of inhalable particles and viscosity of the formulation.
 - b. The acute toxicity data for the 15% formulation are used to support registration of the 7% lotion.
3. In the acute neurotoxicity study, behavioral effects (decreased motor activity) were noted in rats after a single oral dose of 200 mg active ingredient per kg body weight, and effects were temporary with treated rats adapting to the neurological effects after repeated dosing in other studies.
4. The subchronic oral toxicity study in rats demonstrated a no-observed-effect level (NOEL) of 200 mg/kg/day and a lowest-observable-effect level (LOEL) of 1000 mg/kg/day based on the increased incidence of minimal to mild degeneration/regeneration of the olfactory epithelium lining the nasal turbanates of treated male and female rats.
5. No systemic toxicity was observed in the subchronic dermal toxicity study at dose levels up to 1000 mg/kg/day.
6. No adverse effects were observed in a 28-day oral immunotoxicity study or in a developmental toxicity study at oral doses up to 1000 mg/kg/day.
7. No genetic toxicity was observed in bacteria (point mutation assay), an in vitro cytogenetics assay, or in a mouse micronucleus assay. However, a point mutation assay in mouse lymphoma cells reported an increased frequency of point mutations at doses approaching cytotoxic levels without metabolic activation. These results should be confirmed with another assay in a mammalian cell system.
8. An in vitro dermal penetration study indicated that human skin is relatively impermeable (2% of the applied dose) compared to rat skin (78% of the applied dose).

9. Since there were no endpoints indicated in the subchronic dermal toxicity study, and since human skin is relatively impermeable, no endpoints were selected for risk characterizations. The acute neurotoxicity endpoint is appropriate to an incidental oral exposure for children, but because the effect is reversible and pharmacological in nature (reduced activity) and because the label contains instructions to avoid incidental exposure (i.e., licking of fingers and hands), no risk characterization was done for incidental oral scenarios.
10. The only data gap is for a confirmatory gene mutation assay in mammalian cells to determine reproducibility and/or reduce uncertainty associated with the positive results in the mouse lymphoma assay.

I. CHEMICAL AND PRODUCT IDENTITY

A. Background

The active ingredient is a refined, multi-component extract of *Nepeta cataria* which is a member of the mint family of plants (Labiatae). The technical grade active ingredient (TGAI) is identified on proposed product labels as Refined Oil of *Nepeta cataria* and is also referred to as hydrogenated catmint oil (HCO). The plant is commonly known as catnip and is indigenous from eastern Mediterranean to eastern Himalayan regions. The perennial herb can also be grown in North America. Therefore, general information on the nature of the active ingredient is readily available (e.g., <http://chemistry.about.com/library/weekly/aa103001a.htm>; accessed on October 2, 2007) and is summarized as background below.

Nepetalactone is the major component of the refined oil, but there are other components such as pulegic acid with known insect repellent activity. Nepetalactone is a terpene comprised of two isoprene units, and it has a chemical structure similar to that of the valepotriates (from the herb valerian) which have mild central nervous system effects in humans (sedative or stimulant depending on the individual).

The feline behavioral effects of the nepetalactone in catnip are well known, but not all cats respond to the activity of the oil; their sensitivity is inherited (an autosomal dominant gene). Sensitive kittens do not develop responsiveness until they are 3 months old, and young kittens have been known to exhibit avoidance behavior. The variety of responses includes rubbing of the head, chin, cheek or body as well as head shaking or rolling. Sensitive cats may also lick or chew the plant or other source of nepetalactone. These reactions are temporary and can not be induced for an hour or more after exposure. Individual responses vary among sensitive cats. Since the feline receptors for nepetalactone are located in the vomeronasal organ above the cat's palate, the response is associated with the inhalation route of exposure.

Refined Oil of *Nepeta Cataria*
PC Code: 004801

DP Number: 338556, 339493, 339547
EPA File Symbol Number: 71654-EN, 71654-EG, 71654-ER

Historically, catnip has been used in herbal medicine to treat fever, head and tooth aches, colds, colic and spasms in humans. In some individuals catnip can be used to induce sleep, but it can also act as a stimulant in others. At high doses it is emetic in cats and humans. Other historical uses included rubbing meat with catnip leaves, adding it to salads or making tea with it.

Refined Oil of *Nepeta cataria* is being formulated into two lotion products for direct application to human skin to repel biting flies, mosquitoes and other insects. The two concentrations of the active ingredient proposed for these uses are 7% and 15%.

B. Physical and Chemical Properties (Table 1)

The principal insect repellent components in Refined Oil of *Nepeta cataria* are dihydronepetalactone (69.99% w/w) and pulegic acid (6.77% w/w).

Refined Oil of *Nepeta Cataria*
PC Code: 004801

DP Number: 338556, 339493, 339547
EPA File Symbol Number: 71654-EN, 71654-EG, 71654-ER

Table1: Physical and Chemical Properties for Refined Oil of *Nepeta cataria*^a

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Yellow @ 21°C	CCL SOP 10.11
830.6303 Physical State	Liquid @ 21°C	CCL SOP 10.12
830.6304 Odor	Minty	CCL SOP 10.13
830.6313 Stability	Stable @ room and elevated temperatures and in the presence of metals and ions	OPPTS 830.6313
830.6314 Oxidation/Reduction: Chemical Incompatibility	Dihydronepetalactone was relatively stable in solution with metals and metal salts after 14 days at 25°C, with slight decreases at 54°C after 14 days.	
830.6315 Flammability	>99°C	CCL SOP 10.18
830.6316 Explodability	Not addressed	
830.6317 Storage Stability	In short-term testing at 25 and 54°C, dihydronepetalactone content was relatively stable. Guideline study is in progress.	
830.6319 Miscibility	Not applicable, product is not to be diluted in petroleum solvents	
830.6320 Corrosion Characteristics	Guideline study is in progress	
830.6321 Dielectric Breakdown Voltage	Not applicable, product is not for use around electrical equipment	
830.7000 pH	3.97 @ 25°C (1% w/w in deionized water)	CCL SOP 10.17
830.7050 UV/Visible Absorption	Not applicable,	
830.7100 Viscosity	18.09 mm ² /s (cSt) @ 22°C	ASTM D 445 and D446
830.7200 Melting Range	Not applicable, product is a liquid	
830.7220 Boiling Range	266.0 ± 12.0°C	Mettler FP900 Thermosystem
830.7300 Density/Relative Density/Bulk Density	1.0334 @ 20.7°C	Not provided
830.7370 Dissociation Constant in Water	Not applicable, required only for pure active ingredient	
830.7550 Partition Coefficient	Not applicable, required only for pure active ingredient	
830.7840 Water Solubility	0.254 ± 0.013 g/L @ 30°C	OPPTS 7840
830.7950 Vapor Pressure	591, 707, 907, 1100, 1320, and 1630 Pa @ 20, 25, 30, 35, and 40°C, respectively	Terranova 722A diaphragm gauge controller

^aData from MRIDs 46977420, 46977422, 47003102, 47003105

C. Use Pattern

End-use product labels include the following instructions for use:

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

The signal word on the label is CAUTION, and other precautionary statements regarding hazards to humans and domestic animals include:

- Keep out of reach of children.
- Avoid contact with eyes.

First aid statements on the label are as follows:

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.
If in Eyes: <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after five minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for further treatment advice.
If a reaction to this product is suspected: <ul style="list-style-type: none">• Discontinue use.• Take off contaminated clothing.• Wash skin thoroughly with plenty of water.• Call a Poison Control Center or doctor for further treatment advice.
If Swallowed: <ul style="list-style-type: none">• Call Poison Control Center or doctor immediately for treatment advice.• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything by mouth to an unconscious person

II. TOXICITY OF THE TGAI

A. Acute Toxicity

1. Active ingredient (Table 2)

In the acute oral toxicity study (MRID 46977401), one rat dosed at 1750 mg/kg and two dosed at 5000 mg/kg died or were sacrificed for humane reasons on the day of dosing. A surviving rat given 550 mg/kg exhibited no clinical signs of toxicity. Wet fur, lethargy, ataxia, partially closed

or dark eyes, slow or labored breathing, prostrate posture, lacrimation, stained fur/skin, dark extremities, and/or moribundity were noted on the other rats with recovery of the survivors by day 3 of observation.

Ataxia was noted during exposure or immediately after test material removal in the acute dermal toxicity study (MRID 46977402). Wet fur of the inguinal region, leaning, high carriage, absent feces, labored breathing, lethargy, lacrimation, not eating, and/or stained fur around face, perineum, inguen, or abdomen were noted with recovery by day 6 post-dosing.

Male rats in the inhalation study (MRID 44677406) exhibited lethargy, labored breathing and/or hunched posture immediately following exposure. Colored nasal discharge was noted from three males one day post-exposure with recovery by day 3. Lethargy, labored breathing, gasping, hunched posture, incoordination, and/or prostration were noted from two female rats immediately following exposure with recovery by day 4. Colored nasal, oral, or ocular discharge was noted from two females one day post-exposure with recovery by day 7 of observation.

Table 2: Acute Toxicity Profile – Hydrogenated Catmint Oil

Study Type (Guideline)	Species	Results	Toxicity Category	MRID
Acute oral (870.1100)	Rat	LD ₅₀ = 1750 (95% C.L. 455.5-9230) mg/kg (females using the Up-and Down Method)	III	46977401
Acute dermal (870.1200)	Rat	LD ₅₀ > 5000 mg/kg for males, females, and for both sexes combined.	IV	46977402
Acute inhalation (870.1300)	Rat	LC ₅₀ > 5.5 mg/L (males, females, and both sexes combined; 4 hour nose-only exposure)	IV	46977406
Primary eye irritation (870.2400)	Rabbit	Corneal opacity persisted for 24 to 48 hours after treatment with clearance by 72 hours. Iritis was noted at 1 and 24 hours after treatment and cleared by the 48 hour observation. Conjunctival irritation was noted on one rabbit one hour throughout 48 hours after treatment with clearance by 72 hours. The maximum average score was 24.0 at 24 hours after test material instillation. Hydrogenated Catmint Oil was mildly irritating.	III	46977403
Primary dermal Irritation (870.2500)	Rabbit	No dermal irritation or clinical signs of toxicity were observed during the study. The primary irritation index was 0.0.	IV	46977404
Dermal sensitization (870.2600)	Mouse	A local lymph node assay (LLNA) indicated that hydrogenated catmint oil is not a dermal sensitizer.	---	46977405

2. Acute toxicity of the lotion products (Table 3)

A battery of six acute toxicity studies on the 15% lotion indicated the following profile:

Table 3: Acute Toxicity Profile – 15% Hydrogenated Catmint Oil Lotion

Study Type (Guideline)	Species	Results	Toxicity Category	MRID
Acute oral (870.1100)	Rat	LD ₅₀ > 5000 mg/kg (females using the Up-and Down Method)	IV	46977301
Acute dermal (870.1200)	Rat	LD ₅₀ > 5000 mg/kg for males, females, and for both sexes combined.	IV	46977302
Acute inhalation (870.1300)	Rat	The registrant is seeking to waive the requirement for an acute inhalation test. The rationales are: 1) its intended use as an insect repellent lotion for direct application is to the skin, 2) its high viscosity as an oil-water emulsion, and 3) the low vapor pressure and low toxicity of the active ingredient	---*	46977303
Primary eye irritation (870.2400)	Rabbit	Corneal opacity, iritis, or positive conjunctival irritation were not noted on any rabbit during the study. The maximum average score was 4.7 at one hour after test material instillation..	IV	46977303
Primary dermal Irritation (870.2500)	Rabbit	Well defined erythema was noted on 2/3 rabbits one hour after patch removal with reduction to very slight erythema by 24 and 48 hours that cleared by 72 hours. Well defined erythema was noted on another rabbit one hour after patch removal with persistence through 24 hours, reduction to very slight erythema by 48 hours, and clearance by 72 hours.	IV	46977304
Dermal sensitization (870.2600)	Mouse	A local lymph node assay (LLNA) indicated that lotion I is not a dermal sensitizer.	---	46977305
*This data requirement has been waived on the basis of the rationale presented by the Registrant.				

A second product containing 7% active ingredient is also being proposed for registration. No data on that product have been submitted, but the data summarized above will support the second product because the composition of both products is substantially similar (i.e., both products contain the same inert ingredients) based on review of confidential statements of formula (CSF).

3. Acute Neurotoxicity (OPPTS 870.6200)

In an acceptable acute neurotoxicity study (MRID 46977409), groups 12 male or 12 female rats were given a single oral dose of hydrogenated catmint oil (>99% by weight) in corn oil at 0, 40, 200 or 1000 mg/kg body weight. Neurobehavioral assessment (functional observational battery [FOB] and motor activity testing) was performed on all animals pre-dosing and on the day of dosing as well as 7 and 14 days after dosing. Body weight and food consumption were measured weekly throughout the study. At study termination, 6 animals/sex/group were euthanized and

perfused *in situ* for neuropathological examination. Those animals from the control and high dose groups were subjected to histopathological evaluation of central and peripheral nervous system tissues.

No deaths or clinical signs of toxicity were observed and body weight, body weight gain and food consumption were unaffected by treatment. Selected functional observational battery (FOB) results are summarized in Table 4 as follows:

Table 4: Selected FOB results		
Observation	Incidence (number affected/number evaluated)	
	Controls	1000 mg/kg
Males		
Unbalanced swaying and/or uncoordinated gait		
In home cage	0/12	2/12
In open field	0/12	3/12
Abnormal posture	0/12	11/12
Low Arousal	0/12	4/12
No reaction to auditory stimulus	0/12	2/12
Females		
Curled-up posture	1/12	9/12
Appeared to be sleeping	0/12	3/12
Unbalanced swaying and/or uncoordinated gait		
In home cage	0/12	4/12
In open field	0/12	3/12
Slow righting reflex	0/12	11/12
Lacrimation	0/12	2/12
Ataxic gait	0/12	4/12
Low arousal	0/12	2/12
No reaction to auditory stimulus	0/12	8/12
Walking on toes	0/12	2/12

Following the motor activity evaluation, 1/12 males and 1/12 females at 1000 mg/kg vs. none of the controls had slow and/or no pupillary response. Mean hindlimb foot splay was significantly increased in males (33% higher) and females (30% higher) at 1000 mg/kg. Mean body temperature was decreased in males (4% lower) and females (7% lower) at 1000 mg/kg.

On day 1, the cumulative (total) duration of movement was decreased in males and females at 200 mg/kg (19-20%) and 1000 mg/kg (48-52%); the changes were statistically significant in males and females at 1000 mg/kg. The cumulative number of movements on day 1 was decreased in males and females at 200 mg/kg (9-24%) and 1000 mg/kg (35-41%); only the difference in females at 1000 mg/kg was statistically significant.

The LOAEL for acute neurotoxicity of hydrogenated catmint oil in rats was 200 mg/kg based on decreased motor activity on the day of dosing in males and females. The NOAEL was 40 mg/kg.

B. Subchronic Toxicity

1. Oral Toxicity (OPPTS 870.3100)

In an acceptable oral toxicity study (MRID 46977407), hydrogenated catmint oil (HCO) was administered by gavage daily to groups of ten rats/sex at doses of 0, 40, 200, or 1000 mg/kg body weight for 93 days. Hematological, clinical chemistry, urinalysis, ophthalmoscopic, neurological, and microscopic tissue and organ effects were determined only in the subchronic studies.

All rats in the study survived until scheduled sacrifice. The only persistent clinical observation reported was perineal staining throughout the study on three female high-dose rats. No neurological or ophthalmoscopic effects were noted. Total body weight gain was decreased 12% and food efficiency decreased 14% in male rats treated with 1000 mg/kg dose during the study; but no treatment-related effects were found in the remaining groups.

No treatment-related hematological effects were found during the subchronic study. Total bilirubin was slightly increased in high-dose male rats and cholesterol was slightly increased in high-dose male and female rats on study days 48/49 and 92/93. Total urine protein was increased on days 48 and 92 and granular casts were observed on day 92 in all male treatment groups. No increase in urine protein or cast formation was found in female rats.

Centrilobular hepatocellular hypertrophy was statistically significantly increased in male and female rats at the 200 and 1000 mg/kg/day dose level.

A dose-related increase in the incidence and severity of hyaline droplet formation within the epithelium of the proximal convoluted tubule was found in all treatment groups of male rats. In addition, a minimal to mild increase in the incidence of eosinophilic granular casts concomitant with the hyaline droplet formation was found. The casts consisted of multiple focal accumulations of granular material in the tubular lumen near the junction of the inner and outer stripes of the renal medulla. An associated increase in the incidence and severity of minimal to moderate chronic progressive nephropathy was also observed in high-dose male rats.

Minimal to mild degeneration/regeneration of the olfactory epithelium lining the nasal turbinates was observed in high-dose male and female rats. This lesion was characterized by multifocal hypercellularity in the olfactory epithelium at nose levels III and IV due to regeneration of sensory cell nuclei and degeneration of sustentacular cells. In some areas, the olfactory epithelium was thinner than normal but sensory cell nuclei predominated. Sensory or sustentacular

cell necrosis was not apparent and there was no exfoliation of the epithelium or associated inflammation.

The LOAEL for refined oil of *Nepetea cataria*, hydrogenated catnip oil, for male and female rats is 1000 mg/kg/day based on treatment-related effects to the olfactory epithelium. The NOAEL is 200 mg/kg/day for male and female rats.

2. Dermal Toxicity (OPPTS 870.3220)

In an acceptable 28-day dermal toxicity study (MRID 46977415), HCO (purity >99%), was applied to the shaved skin of groups of 10 male and 10 female rats at doses of 0, 100, 500, or 1000 mg/kg/day six hours/day for 29 days.

All rats survived until scheduled sacrifice and no treatment-related effects were found on body weight, body weight gain, food intake, food efficiency, hematology, or clinical chemistry of treated male and female rats. No neurotoxicity was observed.

Treatment-related effects were found only in male rats of all groups and were consistent with hyaline droplet formation. Urine protein excretion was increased 80, 80, and 131% in the low- to high-dose male rats, respectively, and male rats had an increase in urine white blood cells (2/10, 6/10, 9/10, and 9/10, in the control through high-dose group, respectively) and in finely granular casts (0/10, 1/10, 3/10, and 8/10, respectively).

The absolute and relative liver weights of male rats treated with ≥ 500 mg/kg/day were increased 10 – 20% and absolute and relative kidney weights were increased 7-15% in male rats treated with ≥ 100 mg/kg/day. A dose-related increase in minimal to mild hyaline droplet formation within the epithelium of the proximal convoluted tubule was observed microscopically in all groups of treated male rats (0/10, 3/10, 9/10, and 10/10 for the control through high-dose groups, respectively). No treatment-related effects were observed microscopically in the liver; however, the increased absolute and relative liver weights were consistent with hypertrophy.

Very slight to moderate erythema was noted on some animals at the treatment site early in the study, but resolved on all by Day 12. No edema was observed. Epidermal scaling, hyperkeratosis, and epidermal sloughing were also observed at necropsy, but the effects were unrelated to dose.

The dermal LOAEL for male and rats treated with HCO for 29 days was not established in this study. The NOAEL is the highest dose tested, 1000 mg/kg bw/day.

C. Immunotoxicity (OPPTS 870.7800)

In an acceptable immunotoxicity study (MRID 46977407), groups of ten rats/sex were treated by gavage with daily doses of 0, 40, 200, or 1000 mg HCO/kg body weight for 28 days. An additional groups of ten rats/sex received saline (negative control) or 20 mg/kg cyclophosphamide (positive control) daily. On the 22nd day of treatment, all test animals were given an intravenous injection containing sheep red blood cells (SRBC), and at the end of the study, sera were collected and subjected to an enzyme-linked immunosorbent assay (ELISA) to determine if the test material suppressed an immune response.

No effects on humoral immune function were found in HCO-treated male and female rats. All test animals survived until scheduled sacrifice. No neurological, ophthalmoscopic, or other toxicity was noted.

The LOAEL for HCO in male and rats was not established for effects on humoral immune function. The NOAEL for male and female rats was the highest dose tested, 1000 mg/kg/day.

D. Developmental Toxicity (OPPTS 870.3700)

In an acceptable developmental toxicity study (MRID 46977408), HCO (>99%) was administered by gavage to groups of 22 time-mated female rats at doses of 0, 200, 500 or 1000 mg/kg/day in corn oil on gestation days 6 through 20. On gestation day 21 (GD 21), all dams were euthanized and a gross external and visceral examination was performed. The uterus of each pregnant female was removed and the uterine contents were examined and described. All fetuses were removed and individually identified, weighed, sexed, and examined for external and skeletal alterations; approximately one half of the fetuses were examined for visceral and head abnormalities. The total number of fetuses examined (number of litters) was 259 (21), 275 (22), 285 (22), and 256 (21) for the 0, 200, 500, and 1000 mg/kg/day groups, respectively.

There were no treatment-related adverse effects in survival, clinical signs, body weight, or cesarean parameters. Maternal toxicity was limited to reductions in body weight gain (27% and 54%, respectively) and food consumption (~10%) during the first two days of dosing at 500 and 1000 mg/kg/day. These reductions were not considered adverse since they were transient and had no significant impact on overall body weight gain or food consumption for the entire gestation period. Stained fur was observed in the 1000 mg/kg group and was considered possibly test substance-related but not adverse.

Based on the results of this study, the oral maternal toxicity LOAEL for hydrogenated catmint oil in rats was not identified. The maternal NOAEL is 1000 mg/kg bw/day.

There were no treatment-related adverse effects in developmental parameters (deaths/resorptions, fetal weight, developmental alterations) at any dose level tested. Developmental variations common to this strain of rat were observed in the treated and control groups at a similar incidence. No treatment-related malformations were seen.

The oral developmental toxicity LOAEL for hydrogenated catmint oil in rats was not identified. The developmental NOAEL is 1000 mg/kg bw/day.

E. Genetic Toxicity

1. Point mutation assay – bacteria (OPPTS 870.5100)

In an acceptable reverse gene mutation assay in bacteria (MRID 46977410), strains TA98, TA100, TA1535 and TA1537 of *Salmonella typhimurium* and strain WP2 *uvrA* of *Escherichia coli* were exposed to HCO (>99% a.i. by weight) dissolved in DMSO in two independent assays using a standard plate incorporation procedure and duplicate and triplicate plating in the first and second assays respectively. In the first mutagenicity assay, which was called the toxicity-mutation test, concentrations of 0, 33.3, 66.7, 100, 333, 667, 1000, 3333 or 5000 µg/plate were tested with and without S9-mix. In the second assay, which was called the mutagenicity test, concentrations of 0, 333, 667, 1000, 3333 or 5000 µg/plate were tested with and without S9-mix. The S9 fraction was obtained from Aroclor 1254-induced male Sprague-Dawley rat liver.

In the first assay, cytotoxicity was observed at the limit concentration in strain TA1537 both in the presence and absence of S9 mix as well as in strain TA1535 in the presence of S9 mix. In the second assay, cytotoxicity was observed at the limit concentration, and also at 3333 µg/plate, in strain TA1537 both in the presence and absence of S9 mix. Cytotoxicity never caused any more than a slight reduction in the background lawn. No precipitation was observed at any concentration level in either assay. The number of revertants per plate was not increased over the concurrent solvent control value at any test material concentration, with or without S9-mix, in any tester strain. The solvent and positive controls induced the appropriate responses in the corresponding strains. **There was no evidence of induced mutant colonies over background.**

2. *In vitro* mammalian cell point mutation assay (OPPTS 870.5300)

In an acceptable mammalian cell gene mutation assay (MRID 46977413), L5178Y/TK+/- mouse lymphoma cells cultured *in vitro* were exposed for 4 hours to hydrogenated catmint oil (>99% a.i. by weight) dissolved in dimethyl sulfoxide at concentrations of 0, 100, 150, 200, 250, 300 or 350 µg/mL in the absence of mammalian metabolic activation and at concentrations of 0, 300, 350, 425, 500 or 600 µg/mL in the presence of mammalian metabolic activation (S9-mix with S9 fraction from livers of Aroclor 1254 induced male rats).

Hydrogenated catmint oil was tested up to concentrations limited by cytotoxicity, which was clearly demonstrated in a preliminary cytotoxicity assay. There was significant concentration-related cytotoxicity of hydrogenated catmint oil. In the preliminary cytotoxicity assay, precipitation of hydrogenated catmint oil in the culture medium was seen at the end of the 4-hour exposure only at the concentration of 4500 µg/mL, which was the highest concentration tested. Mutant frequencies were significantly increased in the absence of metabolic activation only. Two cultures had mutant frequencies of at least 100 mutants per 10⁶ clonable cells above that of the solvent control, and that extent of an increase is considered biologically significant. Two other cultures, also in the absence of S9 mix, had mutant frequencies between 55 and 99 mutants per 10⁶ clonable cells above that of the solvent control. There was a concentration-related increase in the mutant frequency in the absence of S9 mix. Analysis of colony size distributions showed an increase in the frequency of small colonies in the cultures treated with the test substance. Solvent and positive controls gave appropriate responses. **There was clear evidence of induced mutant colonies over background.**

3. *In vitro* mammalian cell chromosomal aberration assay (OPPTS 870.5375)

In an acceptable mammalian cell cytogenetics assay (MRID 46977411), cultured human peripheral blood lymphocytes were exposed for 4 hours to HCO (>99% a.i. by weight) dissolved in dimethyl sulfoxide (DMSO) at concentrations of 0, 50, 200 or 550 µg/mL without metabolic activation or at concentrations of 0, 210, 420 or 840 µg/mL with metabolic activation, and in both cases the treatment was followed by a 16-hour recovery period so that the total time to harvest was 20 hours after the initiation of treatment. In addition, other cells of this same type were exposed for 20 hours without any recovery period to the same test substance dissolved in DMSO at concentrations of 0, 37.5, 75 or 350 µg/mL without metabolic activation. Metabolic activation was provided by S9 mix with S9 fraction from livers of Aroclor 1254-induced male rats.

HCO was tested up to cytotoxic concentrations based on mitotic indices found in a preliminary cytotoxicity study and concurrently with the cytogenetic assay. At least in the cytogenetic assay, the mitotic index at the highest test concentration was reduced to less than half of that in the solvent control. There were no statistically significant increases over the solvent control values in the percentages of cells with structural aberrations including or excluding gaps at any test material concentration with or without S9-mix. Also there were no increases in numerical aberrations. There was no precipitation of the test substance. Solvent and positive control values were appropriate and within the testing laboratory's historical control ranges for structural chromosomal aberrations and numerical aberrations. **There was no evidence of chromosome aberrations induced over background.**

4. *In vivo* mammalian chromosomal aberration test (OPPTS 870.5395)

In an acceptable mouse bone marrow micronucleus assay (MRID 446977412), groups of 10 mice/sex were given HCO (purity >99% by weight) in a single dose by gavage at 0, 500, 1000, or 2000 mg/kg body weight. Bone marrow cells were harvested from 5 mice/group at approximately 24 or 48 hours after the treatment. Two additional mice/sex/sacrifice time were treated at the highest dose level to observe toxicity and to be in reserve should some of the animals die before bone marrow could be harvested. Because no effect was seen on the frequency of micronucleated polychromatic erythrocytes at any dose of the test substance at 24 hours or at the highest dose at 48 hours, slides were not evaluated for the two lower doses at the 48-hour harvest time. The vehicle was corn oil.

At least one animal treated with HCO at every dose level showed symptoms of toxicity after administration in both the rangefinder experiment and the main experiment. At five and 15 minutes after treatment in the rangefinder experiment on males, all three animals showed ataxia, and two of them showed low posture 15 minutes after treatment. In the rangefinder experiment, no clinical signs of toxicity were observed at 30 or more minutes after treatment. In the main experiment at 2000 mg/kg bw, ataxia was seen in all 14 males and all 14 females, and prostration was observed in two females. At 1000 mg/kg bw, ataxia was seen in seven of the 10 animals treated of each sex, and at 500 mg/kg bw, ataxia was seen in one of the 10 animals treated of each sex. The only sign of moribundity or mortality of the test substance was the death of one female in the high dose group. Polychromatic erythrocytes (PCEs) were examined for micronuclei in five animals/sex/dose level. PCEs were similarly examined in the vehicle control and in the positive control, cyclophosphamide. The vehicle and positive control treatments were also made by oral intubation, and the positive control was examined only at the 24-hour harvest time. Hydrogenated catmint oil was tested at an adequate dose, which was the limit dose for the assay. The positive control induced the appropriate response. There were no statistically significant changes seen in the PCE:NCE ratio. **There was not a significant increase in the frequency of micronucleated polychromatic erythrocytes in bone marrow after any treatment time.** It was concluded that the test chemical was negative in this *in vivo* study.

III. DOSE-RESPONSE ASSESSMENT (Table 5)

Table 5: Toxicity Profile for Hydrogenated Catmint Oil				
Study Type (Guideline)	Species	Dose-Response Information	Effects	MRID
Acute Neurotoxicity (870.6200)	Rat	Doses tested: 0, 40, 200 & 1000 mg/kg NOAEL = 40 mg/kg LOAEL = 200 mg/kg	Deceased motor activity on the day of dosing in males and females	45977409

Table 5: Toxicity Profile for Hydrogenated Catmint Oil

Study Type (Guideline)	Species	Dose-Response Information	Effects	MRID
Subchronic Oral Toxicity (870.3100)	Rat	Doses tested: 0, 40, 200 & 1000 mg/kg/day NOAEL = 200 mg/kg LOAEL = 1000 mg/kg	Minimal to mild degeneration / regeneration of the olfactory epithelium lining the nasal turbinates of males and females	46977407
Subchronic Dermal Toxicity (870.3200)	Rat	Doses tested: 0, 100, 500 & 1000 mg/kg NOAEL = 1000 mg/kg LOAEL > 1000 mg/kg	No adverse effects were reported.	46977415
Oral Immunotoxicity (870.7800)	Rat	Doses tested: 0, 40, 200 & 1000 mg/kg/day NOAEL = 200 mg/kg LOAEL = 1000 mg/kg	No effects reported	46977407
Oral Developmental Toxicity (870.3700)	Rat	Doses tested: 0, 100, 500 & 1000 mg/kg/day <u>Maternal Toxicity</u> NOAEL = 1000 mg/kg LOAEL > 1000 mg/kg <u>Developmental Toxicity</u> NOAEL = 1000 mg/kg LOAEL > 1000 mg/kg	<u>Maternal Toxicity</u> No adverse effects were reported. <u>Developmental Toxicity</u> No adverse effects were reported.	46977408
Reverse Mutation Assay (870.5100)	Bacteria	Doses tested: 0 to 5000 µg/plate with or without metabolic activation (S9 mix)	Negative	46977410
Mammalian cell gene mutation assay (870.5300)	Mouse lymphoma cells	Doses tested: 0 to 3500 µg/mL without metabolic activation (S9) or 0 to 600 µg/mL with metabolic activation (S9 mix)	Mutagenic at doses approaching or at cytotoxic levels without metabolic activation (250 to 350 µg/mL)	46977413
<i>In vitro</i> cytogenetics assay (870.5375)	Human peripheral blood lymphocytes	Doses tested: 0, 50, 200 or 550 µg/mL without metabolic activation or 0, 210, 420 or 840 µg/mL with metabolic activation	Negative	46977411
Bone marrow micronucleus assay (870.5395)	Mice	Doses tested: 0, 500, 1000, or 2000 mg/kg (single oral gavage doses)	Negative	4677412

A. Endpoint Discussion

1. Acute Endpoints

Results of the acute oral toxicity study with the active ingredient (MRID 46977401) characterized effects at higher single oral doses as follows:

Death occurred on the day of dosing in one of the three rats dosed at 1750 mg/kg and one of two rats dosed at 5000 mg/kg. The remaining rat dosed at 5000 mg/kg was sacrificed for humane reasons on the day of dosing. No clinical signs were observed in the rat at 550 mg/kg. Clinical signs observed in the remaining rats included wet fur, lethargy, ataxia, partially closed or dark eyes, slow or labored breathing, prostrate posture, lacrimation, stained fur/skin, dark extremities, and/or moribundity. No clinical signs were observed by test day 3 (in surviving rats). No body weight losses occurred after dosing. No gross lesions were present in the rats at necropsy.

The only clinical sign noted in an acute oral toxicity study with the 15% lotion (MRID 46977301) was "high carriage" in one of three rats given the 5000 mg/kg dose. No other effects on body weight or incidence of gross lesions were noted in the study.

Dermal application of 5000 mg/kg to a group of 5 male rats had no effects, but the same dose applied to skin of 5 female rats had effects described in the study report (MRID 46977402) as follows:

The female rats exhibited lethargy, ataxia, absent feces, labored breathing, lacrimation, stained fur/skin, wet fur, not eating, high carriage, and/or leaning. Ataxia was observed only during the exposure period or immediately after test substance removal. The remaining clinical signs cleared by test day 6.

No clinical signs of toxicity were observed in male and female rats dermally exposed to 5000 mg of the 15% lotion per kg body weight (MRID 46977302).

After a 4-hour nose only exposure of 5 male and 5 female rats to air containing 5.5 mg HCO/L, clinical signs were described (MRID 46977406) as follows:

All animals...survived the exposure and the subsequent recovery period...

Notable clinical signs of toxicity...included lethargy, labored breathing, gasping, hunched or prostrate posture, and incoordination immediately following exposure which lasted for 1 to 3 days postexposure for males and females, respectively...

It should be noted that clinical signs similar to those described in acute toxicity studies were reported in the 90-day subchronic oral toxicity study (MRID 46977407). These effects were described as follows:

At 200 mg/kg/day, two males (of 10) were lethargic on the second day of dosing. At 1000 mg/kg/day, nine males and six females were lethargic and four males and one female were ataxic during this period. All of these post-dosing observations were transient in that they resolved prior to the next dose and were not observed beginning on dosing day 3 through the end of the study.

At similar low doses, an acute neurotoxicity endpoint of 40 mg/kg was characterized by decreased motor activity on the day of dosing. These effects were not observed after repeated oral doses at similar levels, and no histopathology was found in nervous tissues from treated animals in the acute or subchronic neurotoxicity studies. In addition, the subchronic dermal toxicity study did not present histopathological effects in the nasal cavity or changes in neurological parameters after repeated dermal exposures up to 1000 mg/kg/day.

These studies indicate:

- The clinical signs observed at lethal oral doses (1750-5000 mg/kg) are not seen at single doses that are 3 to 10-fold lower (550 mg/kg) which suggest a steep dose-response curve.
- Acute oral toxicity study results with the 15% lotion appears to reduce the likelihood that neurological clinical signs will occur.
- Acute studies by dermal or inhalation routes also appear to reduce the chances of seeing the clinical signs of concern.
- Lower non-lethal doses (200-1000 mg/kg) decreased motor activity, and results from subchronic studies suggest the effects are reversible and that rats can adapt to these effects even when dosing is continued.

Therefore, the acute neurotoxicity NOEL is appropriate only in the assessment of incidental oral exposure scenarios for the insect repellent products considered in this assessment.

2. Subchronic Endpoints

Effects noted in the subchronic oral toxicity study showed adaptive changes in the liver (centrilobular hepatocellular hypertrophy) and a sex-related (males only) species specific (rats) kidney effects (hyaline droplet formation and associated nephropathy) at the highest dose tested (1000 mg/kg/day). The 1000 mg/kg/day dose level was associated with significant degenerative/regenerative changes in the nasal cavity of treated rats, and the NOEL was 200 mg/kg/day. **Because no similar toxicity was observed in the 28-day dermal toxicity study, the 1000 mg/kg/day NOEL will be used to assess short and intermediate-term dermal exposures to the insect repellent products.**

No developmental toxicity or immunotoxicity was noted in rat studies using the same dose levels as those used in subchronic toxicity studies.

IV. Exposure Assessment

A. Use Patterns and Appropriate Endpoints

As indicated previously, the two lotion product labels include the following instructions for use:

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adult's hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

The products contains 7 or 15% active ingredient, and the application rate is based on dosimetry information reported in product performance studies (MRID 47015602). The application rates are determined as follows:

$$0.63 \text{ g product}/250 \text{ cm}^2 \text{ for 15\% lotion} = 2.52 \text{ mg product}/\text{cm}^2$$

$$(2.52 \text{ mg}/\text{cm}^2)(0.15) = 0.378 \text{ mg active ingredient}/\text{cm}^2$$

The endpoints appropriate for this type of insect repellent use are as follows:

Endpoint Summary

Scenario	Study Type	NOEL/LOEL	Effects	MRID
Acute (Incidental Oral)	Acute Neurotoxicity	40/200 mg/kg	Deceased motor activity on the day of dosing in males and females	45977409
Short- & Intermediate Term	28-Day Dermal Toxicity	≥ 1000 mg/kg/day	No adverse effects noted.	46977415

NOEL = no-observed-effect level; LOEL = lowest-observed-effect level.

No uncertainty factors are specified and no further exposure assessment is conducted because:

- Labeling cautions against application of products to the hands of children or allowing children to apply the lotions themselves, and
- Subchronic dermal toxicity studies did not indicate systemic toxicity after repeated dermal exposure of rats to a limit dose of 1000 mg/kg/day.

B. Dermal Penetration Study (OPPTS 870.7600)

In an *in vitro* dermal penetration study (MRID 47015601), HCO (purity 99%) was applied to twelve 0.64 cm² sections of male rat skin and twelve 0.64 cm² sections of human cadaver skin for eight hours at 30,000 µg/cm². The skins specimens were contained in dual-chambered diffusion

cell assemblies. Receptor fluid samples were collected 0.5, 1, 2, 4, 6, 8, and 24 hours after the start of dosing. After eight hours of exposure, the skin specimens were washed with ethanol and tape stripped. All wash, receptor fluid samples, tape strip samples, and skin specimens were analyzed for HCO.

Penetration rates of HCO through rat skin were ~105 – 110-fold greater than through human skin during the initial *in vitro* eight hour exposure. The penetration rates declined approximately 18-fold for rat skin during the 16-hour post-exposure period, but was still approximately five-times greater than the rates reported for human skin. At the end of the study, the total absorbable dose was ~78% for rat skin and ~2% for human skin. While penetration rates through rat skin declined following removal of the test material, penetration rates through human skin were comparable during and after exposure. Total recovery of the test material for skin from both species and all time intervals was $\geq 89\%$.

Results from the oral and dermal subchronic toxicity studies (incidence of microscopic changes noted in the kidneys of male rats) suggest that dermal absorption is likely to be $>20\%$ based on comparison of the LOELs from the two studies ($[\text{oral LOEL}/\text{dermal LOEL}] \times 100$). The *in vitro* dermal penetration study with rat and human skin indicated a high degree of penetration in rat skin (78% of the dose after an eight-hour exposure) while human skin was relatively impermeable (2% of the dose was absorbed during the same exposure period) to hydrogenated catmint oil. It should be noted that the application rate for the active ingredient in the dermal penetration study is similar to that determined from the 15% lotion's product performance study (approximately 80% of the product application rate).

B. Occupational and Residential Exposure

No occupational estimates are made in this assessment since HCO is to be used by individuals as an insect repellent that they apply directly to their own skin. Non-occupational dermal exposure estimates were not determined because the subchronic dermal toxicity study did not demonstrate an endpoint for use in risk characterization, human skin is much less permeable to HCO than rat skin (MRID 47015601), and the label indicates that advice from a physician or Poison Control Center should be sought when reactions to exposure from use of the products are suspected. Again, the directions for use on the two product labels indicated that application of the lotions to children's fingers and hands was to be avoided. Therefore, no exposure estimates were determined for incidental oral exposure.

V. RISK CHARACTERIZATION

Based on the absence of short- and intermediate-term toxicity endpoints, very low dermal penetration in humans, and precautionary labeling to avoid the likelihood of incidental oral exposure for small children, no risk characterizations are needed in this assessment.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

MAY 21 2007

DATE: May 21, 2007

SUBJECT: Science Review of Product Performance in Support of the Registration.

Decision Number: 371862
DP Number: 338694
EPA File Symbol Number: 71654-ER and 71654-EG
Chemical Class: Biochemical
PC Code: 004801
CAS Number: 8023-84-5
Active Ingredient Tolerance Exemptions: No tolerance exemption. Non- food product.
MRID Numbers: 469774-24, 469774-25 and 470156-02

FROM: Clara Fuentes, Ph. D. Biologist
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

DuPont Chemical Solutions Enterprise requests registration of end-use products, *Refined Oil of Nepeta Cataria 15% Lotion* (EPA Reg. No. 71654-ER), and *Refined Oil of Nepeta Cataria 7 % Lotion* (EPA Reg. No. 71654-EG), containing 15 % w/w and 7 % w/w of new active ingredient, respectively, of hydrogenated catmint oil (also known as refined oil of *Nepeta cataria*). The new products proposed for registration are intended for use as personal skin-applied insect repellents against mosquitoes and black flies. In support of this registration, the registrant has submitted copies of product labels, CSFs and MRIDs 469774-24, 469774-25, and 470156-02.

1. Product chemistry data (CSF) are acceptable pending resolution of the deficiencies identified below:

- 1a. Deficiency #1: The CAS number, [REDACTED]
[REDACTED] respectively, are unknown to the Agency.

2. Product Performance data are acceptable pending clarification on the following items:

- 2a. The study report needs to provide a detailed discussion on the statistics employed to analyze the data.
 - 2b. There is no written study report for these studies, except a brief summary of results and conclusions. The description of the study methods are referenced back to the original protocol. Protocol deviations are not addressed.
 - 2c. The inconsistencies concerning amount of test material applied to subjects need to be resolved (Refer to "Reviewer's comments" at the end of this memo).
 - 2d. It is not clear whether the landing rates for the whole body counts are based on 1 minute exposure taken hourly for 1. This information on landings rate does should appear on the results table (Appendix IV).
 - 2e. The test sites were not monitored for incidence of mosquito-borne diseases prior to testing there. Although this is not a scientific issue, it has ethical implications.
 - 2f. Complete Protection Time can be estimated from landings rather than bites, to minimize subjects' exposure to mosquito bites in the field. It is reported in these studies that the endpoint was bites, and subjects were continuously exposed to mosquitoes throughout the entire duration of the test. Although this approach does not compromise the scientific validity of the data, it has ethical implications.

STUDY SUMMARIES

Product Chemistry

The only product chemistry reviewed herein is the information provided on the CSF dated 4/12/06. No inert ingredient is in list 1. All inert ingredients are in lists 3, 4A, and 4B. None of

the inert ingredients are exempt from the requirement of tolerance. This is a non-food product to be used as insect repellent. The lower and upper certified limits are within acceptable range. The active ingredient statement on the label matches the CSF. pH = 6.09 at 25°C for product 71654-EG, and pH = 5.54 at 25°C. Flash point/flammability > 97°C for both products.

Product Performance

MRDs 469774-24 and 469774-25, and 470156-02

Introduction

The objective of studies 469774-24 and -25 is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against mosquitoes in the field. The test sites were at Nicatous Lodge, Maine, and Collier Seminole State Park, Florida. The type of habitat at these sites are not described in the study reports. The main species of mosquitoes found in Maine was *Ochlerotatus intrudens*. The primary mosquito species found at the Florida site were: *Ochlerotatus atlanticus*, *O. taeniorhynchus*, *Psorophora ferox* and *Culiseta melanura*. Environmental conditions recorded during the studies were within acceptable limits.

The objective of study MRID 470156-02 is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against black flies in the field. The test site was at Nicatous Lodge, Maine. The type of habitat at this site was not described in the study report. The main species of black flies found at the study site was *Simulium decorum*. The Environmental conditions recorded during the study were within acceptable limits

Results and Conclusions

MRID 469774-24:

The average number of landings on each control subjects were 14.6 and 17.1 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.4 landings, ranging from 11 to 41 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 8 hours with no deviations (n=10)

The mean CPT for the Liquid (15 % w/w) was 7.48 hours \pm 0.26 (n=10)

The mean CPT for the Lotion (7 % w/w) was 7.33 hours \pm 0.33 (n=5)

The mean CPT for the Lotion (7 % w/w) was 4.17 hours \pm 1.58 (n=5)

MRID 469774-25:

The average number of landings on each control subjects were 12.1 and 20.4 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.9 landings, ranging from 7 to 49 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 6.14 hours \pm 1.05 (n=10)

The mean CPT for the Liquid (15 % w/w) was 5.14 hours \pm 0.22 (n=10)

The mean CPT for the Lotion (7 % w/w) was 5.54 hours \pm 1.34 (n=5)

The mean CPT for the Lotion (7 % w/w) was 4.17 hours \pm 0.42 (n=5)

MRID 470156-02:

The mean number of landings on each control subjects were 21.7 and 29.6, ranging from 3 to 42 during session 1, and 20.3 and 24.3, ranging from 1 to 56, during session 2. These counts are per 5 minutes exposure. The mean count of landings on whole body suit was 26.3, ranging from 14 to 47 landings during session 1, and 27.2 landings, ranging from 2 to 37, during session 2. These whole body suit counts were taken hourly during 8 hours of intermittent exposure (Appendix IV: statistics. Pg. 99 of 140). The duration of the whole body suit exposure periods are not specified in the report.

Session 1 and 2: Mean CPT for the Lotion (15 % w/w) = 7.31 (\pm 0.56) hours (n=10)

Session 1 and 2: Mean CPT for the Liquid (15 % w/w) = 7.32 (\pm 1.09) hours (n=10)

Session 1 and 2: Mean CPT for the Lotion (7 % w/w) = 6.59 (\pm 0.26) hours (n= 5)

Session 1 and 2: Mean CPT for the Liquid (7 % w/w) = 5.54 (\pm 2.28) hours (n=5)

Reviewer Comments:*MRIDs 469774-24 and 469774-25*

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, one site in Maine and another site in Florida. The report does not describe the different habitat characteristics at these 2 test sites. The report provides information on the species, and abundance of mosquito species found at each site. The environmental data shows that the weather was cloudy, humid and on the cold side in Maine (average temperature was high fifties and low sixties ° F); RH was between 80 and 94; and the wind speed was less than 1 MPH. The weather data from Florida shows that it was sunny for the first 4 hours of the test, and then it became cloudy with 100% cloud cover. Raw

data collection sheet indicates that it started raining at the last 2 hours of the test. Apparently, this did not interfere with mosquito activity. The temperature was between 75 and 90 ° F, and RH was between 70 and 96. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

Neither Maine nor the Florida site was monitored for incidence of mosquito borne diseases prior to conducting the study. Site selection was based solely on unobstructed space, abundance and diversity of mosquito species, and mosquitoes' landing rate. All the mosquito species identified at these sites are potential vectors of WNV. While this is not a scientific issue, it has ethical implications.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test material applied to subjects. On page 7 of 104, it is stated that the lotions will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area for the 15% and 7% formulations, respectively. On pages 13 and 16 of 104, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the liquid 15% formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 104 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The whole body count of mosquito landings was taken hourly for unspecified exposure periods throughout the study. The table on page 66 of 104 shows hourly counts and the mean of those landings: 20.9 average landings. It is stated on page 8 of 104, that these counts are per minute. Also on page 8 of 104, it is reported that the landing counts on untreated skin of test subjects are recorded as number of landings per 5 minutes exposure. The information regarding landings rate should be reported on the table.

The endpoint in this study was the First Confirmed Bite, with subjects being continuously exposed to mosquitoes in the field. Frequency of mosquito landings is a good indicator of repellent breakdown. Risk to subjects from continuous exposure to mosquitoes in the field can be minimized by changing the endpoint from bites to landings, and exposing subjects to mosquitoes intermittently for short periods of time.

According to the study protocol, two test substances will be tested simultaneously on separate arms of the same subject. EPA specifically discourages testing more than one product on the same subject, unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2

concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

MRID 470156-02

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, in Maine during 2 separate test sessions. Each test session lasted 8 hours. The report does not describe the different habitat characteristics at these 2 test sites. The predominant black fly species collected at these sites is *Simulium decorum*. The environmental data shows that the weather was sunny at the first day session, and cloudy the second. RH was not recorded the first day session; for the second day session, the RH was between 58 and 88, and the temperature was in the high fifties and seventies ° F. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test material applied to subjects. On page 7 of 140, it is stated that the lotion formulations, 15% and 7% w/w of a. i. will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area, respectively, and the liquids formulations will be applied as 43 g / 250 sq. cm. On pages 13 and 16 of 140, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the 15 % liquid formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 140 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The endpoint in this study was the First Confirmed Landing, with subjects being continuously exposed to black flies in the field. To evaluate efficacy against black flies, landings will be used instead of bites due to the painful nature of black fly bites.

According to the study protocol, two test substances will be tested simultaneously on separate legs of the same subject. EPA specifically discourages multiple tests on the same subject unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

The protocol, on page 15 of 140, states that if the period of black fly activity were less than 8 hours, subjects would be treated early enough before black fly activity began. The report does

not indicate that subjects were treated well in advance to initiation of the study because the landing rates were considered acceptable over the length of the study period (pg. 10 of 140). There were only 3 exposure periods during the study showing landing rates below 1 landing per minute. This occurred at 2 and 3 hours after test initiation. The conclusion is that if repellency lasted longer than that period, the products would have been effective during those periods as well.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2 concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

cc: *Reviewer name*, Clara Fuentes
RAL name, Raderrio Wilkins
BPPD Chron File, IHAD/ARS
Date: May 21, 2007



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

December 27, 2006

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
EXPERIMENTAL STATION (ESL402/3224C, PO Box 80402
WILMINGTON, DE 19880-0402

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 27-DEC-06. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S:	803055	Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No	<div>Print Letter</div> <div>Enter More Information</div> <div>Tracking</div>
Application Type:	Pending Product Amendment	Eligible:	<input checked="" type="radio"/> Yes <input type="radio"/> No			
Company:	71654 E.I. DUPONT DE NEMOURS, AND COMPANY	V				
Risk Manager:	Biological & Pollution Prevention Division, PM Team S1					
Product #:	71654-EG	Product Name:	REFINE OIL OF NEPETA CATARIA 7% LOT			
Overline #:						
MS Tab	Section 3	MS Tab	Product Name:			
Application Date:	19-Dec-2006	ic	OPP Rec'd Date:	27-Dec-2006	ic	<div>Receipt Content</div> <div>Study</div>
Front End Date:	27-Dec-2006	ic	Risk Manager Send Date:	27-Dec-2006	ic	
FFS Due Date:			Negotiated Due Date:			
OPP Target Date:						
Fast Track:	<input type="checkbox"/>		ic			
Receipt Description:	physical & chemical characteristics					
Form A:	<input type="checkbox"/>	Signature Line:		Form B:	<input type="checkbox"/>	Signature Line:

No PC Codes

New AI Lead -

Paula for preparation
AK

B67 7% Lotion

Denise

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



TRANSMITTAL LETTER

December 19, 2006

Dr. Russell Jones
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent
"Refined Oil of *Nepeta cataria* 7% Lotion"; EPA File Symbol : 71654-EG

This letter and its attachments contain new data inadvertently omitted from the initial submission of the subject application.

Three copies of the following report are attached:

47013901 *Physical and Chemical Characteristics of 7wt.% Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH*
EPA Guidelines 830.6303, 830.6315 and 830.7000
David J. Sinning
August 28, 2006
7 pages

Should you have any questions please feel free to call.

Sincerely,

Thomas C. McEntee / Kdj

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 696-6856
(978) 887-6200 Alternate

Registrant
Name of Company
Address of Company

RE: **Product Name: Refined Oil of Nepeta cataria (7% ^{hation} formulation)**
EPA File Symbol/Reg. No: 71654-EG
Application dated: December 19, 2006
PRIA Category: B-60

Dear [Enter Contact Name]:

The application referred to above, submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended, and the Pesticide Registration Improvement Act (PRIA) has been preliminarily screened for administrative and scientific completeness by the Biopesticides and Pollution Prevention Division. Your submission has failed the screen for [administrative, scientific] completeness for the reasons below:

1. **Administrative Deficiencies**

a. Applications for registration must address all Tier I data requirements (product chemistry, toxicology and non-target organism, fate and expression) for biochemical pesticides per 40 CFR 158.690. These data requirements must be addressed either with the submission of data or with a request to waive testing justified by a valid scientific rationale or by stating that the study is not applicable. The data matrix form 8570-35 should indicate how each data requirement will be satisfied.

- In the CSF AI is listed as the refined Oil , 4 of the [redacted] inerts were not found cleared
- Formulators exemption form is absent^x
- **The requested bridge of the requirements of the 7% formulation to the 15% formulation data can not be made at this time due to the absence of the 15% formulation data with the submission.**
-
- **Scientific Deficiencies**
- **Only a part of the chemistry data were submitted with this submission.**
- **The irritation and immune responses to the formulations may require further testing since this requested use is directed to be applied to the**

human .

The data were referred to be those of the 15% formulation but were not submitted with this package.

The subject application (PRIA Category Code **B 60**) has a decision due date of [**enter due date**]. At this time, the application is considered incomplete until you address all of the deficiencies identified in this letter. Per 40 CFR 152.105, your application will be administratively withdrawn without further notice to you if you do not submit the missing information within 75 days from the date of this letter. However, submission of the above information by or on the 75 day due date (**enter calculated time**) will not allow BPPD enough time to process, conduct review and make a regulatory decision by the PRIA due date of [**enter due date**]. Therefore, BPPD requires that all deficiencies as stated above be addressed and resubmitted to the Agency within [**enter timeframe**] days from the date of this letter. Please submit the above materials immediately to Linda Hollis by fax (703) 305-0118 or hollis.linda@epa.gov .

Sincerely,

Janet L. Andersen, Ph.D.
Biopesticides and Pollution Prevention Division
7511C

DATA EVALUATION RECORD

EPA Primary Reviewer: Clara Fuentes, Ph.D.

STUDY TYPE: Product performance (OPPTS 810.3700)

MRID NUMBER: 470156-02

PROJECT NUMBER: 0306-313-0141

SPONSOR: E.I. DuPont de Nemours and Company
DuPont Research and Development
PO Box 80328
Route 141- Between 52 & 202, building 328
Wilmington, DE 19880-0328

PROTOCOL NUMBERS: G3130306002A121

STUDY INITIATED: March 21, 2006

STUDY COMPLETED: September 19, 2006

STUDY TITLE: *Evaluation of the Efficacy of Personal Repellents
Against Black Flies in Maine.*

AUTHOR/STUDY DIRECTOR: Niketas C. Spero

TESTING FACILITY: Insect Control and Research, Inc.
1330 Dillion Heights Ave.
Baltimore, MD. 21228-1199

CONFIDENTIALITY CLAIMS: No data confidentiality claims

GOOD LABORATORY PARCTICES STATEMENT:

Signed GLP statement is provided. Sample stability data was not provided by sponsor.

TEST MATERIALS:

LOTIONS 1630802C 15% w/w *hydrogenated catmint oil*,
1630802D 7% w/w *hydrogenated catmint oil*.

LIQUIDS 1630703B 15% w/w *hydrogenated catmint oil*,
1630703C 7% w/w *hydrogenated catmint oil*.

I. STUDIES' SUMMARY:

The objective of this study is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against black flies in the field. The test site was at Nicatous Lodge, Maine. The type of habitat at this site was not described in the study report. The main species of black flies found at the study site was *Simulium decorum*. The Environmental conditions recorded during the study were within acceptable limits.

Efficacy was expressed as the average Complete Protection Time (CPT) from time of application of the repellents to First Confirmed Landing (FCL). A landing is recorded when the black fly lands and remains on the treated surface for 2 seconds. A first landing is confirmed when followed by a second landing within 30 minutes apart from the first one. The criteria for breakdown was 2 sequential landings 30 minutes apart from each other (pg. 8 of 140). The whole body count on the control subject ranged from 14 to 47 landings per minute during the first session, and from 2 to 71 landings per minute during the second session (Appendix III). According to the study protocol, whole body counts will be taken at initiation of the study and then hourly (pg. 17 of 140). The exposed 250 sq. cm skin of the 2 control subjects received from 3 to 70 landings per five minutes exposure periods during session 1, and from 1 to 56 landings per 5 minutes exposure periods during session 2 (Appendix III and IV). Controls exposed their legs (250 sq. cm. untreated skin) intermittently for 5 minutes every half an hour throughout the test (pg. 17 of 140). The test lasted 8 hours (pgs. 8 and 10 of 140). According to the study protocol, pg. 17 of 140, "Efficacy will be evaluated by continuous exposure of the test subjects' legs."

The lotion formulation containing 15 % w/w active ingredient was applied at a dose of 0.63 g per 250 sq. cm of subject's skin surface area. The lotion formulation containing half that concentration of active ingredient (7 % w/w) was applied at a dose of 0.64 g per 250 sq. cm of subject's skin surface area. Liquid formulations at 15 % w/w and 7 % w/w were both applied at the same dose of 0.43 ml per 250 sq. cm of skin surface area to ensure full coverage (pg. 7 of 140). On page 16 of 140, it is stated that the amount of formulations applied were 62 g and 0.4 g / 250 sq. cm of skin for lotions and liquids, respectively.

These formulations were tested individually and simultaneously on separate legs of the same test subjects. Subjects were treated in pairs (pg. 17 of 140). Treatment formulations containing the highest concentration of active ingredient (15 % w/w) were replicated on 10 test subjects. Formulations containing half that concentration of active ingredient (7 % w/w) were also tested individually and simultaneously on 5 additional subjects (pg. 8 of 140).

The Lotion formulation, containing 15% w/w of *hydrogenated catmint oil*, provided an average of 7.31 (\pm 0.56) hours of protection. The Liquid formulation, containing the

same concentration of active ingredient (15% w/w), provided 7.32 (\pm 1.09) hours of protection (These averages include both study sessions). The lotion and liquid formulations containing 7 % of the active ingredient provided approximately 7 (\pm 1.48) hours of protection, and 6 (\pm 2.28) hours of protection, respectively (pg. 9 of 140). The data was not statistically analyzed for comparison of treatment means.

II. STUDY DESIGN

The study was conducted as described in the study protocol (G3130306002A121), except for 2 deviations: 1) the lotion formulations were not applied by weight as proposed on the test protocol. Due to the limited amount supplied by the sponsor, an applicator stick was inserted directly into the sample container and then, the sample container with the applicator were placed on scale rather than placing sufficient material in a weigh pan, including the applicator stick, and then placing the weigh pan on the scale (pages 7 and 27 of 140). A new applicator was used for each subject as described in the protocol. 2) Characterization of sample is not included in the final study report as specified in the protocol. ICR retains that information in their facility (pages 7 and 27 of 140).

The protocol proposed at least 2 test sites, in Maine. The sites selection was based on unobstructed space, mosquito species composition and landing rates in the range of 1 to 10 landings per minute on a 250 sq. cm of exposed skin. As stated on the study protocol, landing rates on test site selection will be monitored by support staff and/or the study Director, who will expose their untreated leg at likely sites through the area (pg. 15 of 140). The protocol proposes 12 subjects per test, 2 of which will be randomly chosen to serve as controls. Control subjects will expose 250 sq. cm of untreated leg skin intermittently for 5 minutes every half an hour throughout the course of the study. During the test, a whole body count of black flies landing on one of the controls will be taken at initiation of the test, and then hourly during the course of the study. Test subjects will expose treated areas (250 sq. cm.) of their legs continuously for 8 hours or until First Confirmed Landing occurs (pg. 17 of 140).

As specified on the study protocol, subjects will prepare their legs for repellent treatments prior to arrival at the field site. Repellent treatments will be randomly applied to subjects at the vicinity of the test site. It is stated on page 16 of 140 of the study protocol that the amount of repellent applied per subject per treatment will be 0.4 g. of liquid formulation, and 0.62 grams of the lotion formulation. The liquid formulation will be applied using a syringe. The lotion formulation will be applied by weight using a stick applicator. This procedure is described further on the same page: "The container with the lotion formulation will be placed on a scale including an applicator stick, and the scale will be tared. Each time the negative value of 0.62 g appears on the scale, the target weight would have been applied using an applicator stick." (pg. 16 of 140).

Subjects will be treated in pairs, each member of a pair will be treated with one formulation, and then the other formulation. The starting time to CPT will be the lapse of time from application of the second repellent formulation to time of first confirmed landing (pg. 17 of 140). Landing black flies will be aspirated and held for subsequent identification (pg. 18 of 140). This study includes 2 sessions of 8 hours each (pg. 18 of 140).

Appropriate statistical analysis will be conducted. Efficacy data will be reported as mean hours and minutes of complete protection (pg.19 of 140).

This protocol was amended for additional testing of liquid and lotion formulations containing 7% active ingredient. Five additional subjects were used for evaluating these 2 formulations simultaneously. Each subject will test both formulations, each of them on separate limbs. On page 25 of 140, it is stated that the formulations were tested on subjects' arms. On page 8 of 140, it is reported that the performance of the 15 and 7 percent formulations, lotion and liquid, were tested on subjects' legs.

III. RESULTS AND CONCLUSIONS

The mean number of landings on each control subjects were 21.7 and 29.6, ranging from 3 to 42 during session 1, and 20.3 and 24.3, ranging from 1 to 56, during session 2. These counts are per 5 minutes exposure. The mean count of landings on whole body suit was 26.3, ranging from 14 to 47 landings during session 1, and 27.2 landings, ranging from 2 to 37, during session 2. These whole body suit counts were taken hourly during 8 hours of intermittent exposure (Appendix IV: statistics. Pg. 99 of 140). The duration of the whole body suit exposure periods are not specified in the report.

Session 1 and 2:	Mean CPT for the Lotion (15 % w/w) = 7.31 (± 0.56) hours (n=10)
Session 1 and 2:	Mean CPT for the Liquid (15 % w/w) = 7.32 (± 1.09) hours (n=10)

Session 1 and 2:	Mean CPT for the Lotion (7 % w/w) = 6.59 (± 0.26) hours (n= 5)
Session 1 and 2:	Mean CPT for the Liquid (7 % w/w) = 5.54 (± 2.28) hours (n=5)

IV. REVIEWER COMMENTS

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, in Maine during 2 separate test sessions. Each test session lasted 8 hours. The report does not describe the different habitat characteristics at these 2 test sites. The predominant black fly species collected at these sites is *Simulium decorum*. The environmental data shows that the weather was sunny at the first day session, and cloudy the second. RH was not recorded the first day session; for the second day session, the RH was between 58 and 88,

and the temperature was in the high fifties and seventies ° F. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test material applied to subjects. On page 7 of 140, it is stated that the lotion formulations, 15% and 7% w/w of a. i. will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area, respectively, and the liquids formulations will be applied as 43 g / 250 sq. cm. On pages 13 and 16 of 140, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the 15 % liquid formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 140 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The endpoint in this study was the First Confirmed Landing, with subjects being continuously exposed to black flies in the field. To evaluate efficacy against black flies, landings will be used instead of bites due to the painful nature of black fly bites.

According to the study protocol, two test substances will be tested simultaneously on separate legs of the same subject. EPA specifically discourages multiple tests on the same subject unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

The protocol, on page 15 of 140, states that if the period of black fly activity were less than 8 hours, subjects would be treated early enough before black fly activity began. The report does not indicate that subjects were treated well in advance to initiation of the study because the landing rates were considered acceptable over the length of the study period (pg. 10 of 140). There were only 3 exposure periods during the study showing landing rates below 1 landing per minute. This occurred at 2 and 3 hours after test initiation. The conclusion is that if repellency lasted longer than that period, the products would have been effective during those periods as well.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2 concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

DATA EVALUATION RECORD

EPA Primary Reviewer: Clara Fuentes, Ph.D.

STUDY TYPE: Product performance (OPPTS 810.3700)

MRIDs NUMBERS: 469774-24 and 469774-25

PROJECT NUMBERS: 0306-313-0142 and 0306-313-0143

SPONSOR: E.I. DuPont de Nemours and Company
DuPont Research and Development
PO Box 80328
Route 141- Between 52 & 202, building 328
Wilmington, DE 19880-0328

PROTOCOL NUMBERS: G3130306002A121 and G3130306002A044

MRID 469774-24 STUDY INITIATED: March 21, 2006

MRID 469774-24 STUDY COMPLETED: September 19, 2006

MRID 469774-25 STUDY INITIATED: March 7, 2006

MRID 469774-25 STUDY INITIATED: September 19, 2006

STUDY COMPLETED: September 19, 2006

MRID 469774-24 STUDY TITLE: *Evaluation of the Efficacy of Personal Repellents
Against Mosquitoes in Maine.*

MRID 469774-25 STUDY TITLE: *Evaluation of the Efficacy of Personal Repellents
Against Mosquitoes in Florida.*

AUTHOR/STUDY DIRECTOR: Niketas C. Spero

TESTING FACILITY: Insect Control and Research, Inc.
1330 Dillion Heights Ave.
Baltimore, MD. 21228-1199

CONFIDENTIALITY CLAIMS: No data confidentiality claims

GOOD LABORATORY PARCTICES STATEMENT:

Signed GLP statement is provided. Sample stability data was not provided by sponsor.

TEST MATERIALS:

LOTIONS 1630802C 15% w/w *hydrogenated catmint oil*,
 1630802D 7% w/w *hydrogenated catmint oil*.

LIQUIDS 1630703B 15% w/w *hydrogenated catmint oil*,
 1630703C 7% w/w *hydrogenated catmint oil*.

I. STUDIES' SUMMARY:

The objective of these studies is to evaluate the efficacy of 4 repellent formulations, containing different concentrations of the same active ingredient, *hydrogenated catmint oil* (CAS #8023-84-5; PC Code: 004801, also known as *Nepeta catia*) against mosquitoes in the field. The test sites were at Nicaus Lodge, Maine, and Collier Seminole State Park, Florida. The type of habitat at these sites are not described in the study reports. The main species of mosquitoes found in Maine was *Ochlerotatus intrudens*. The primary mosquito species found at the Florida site were: *Ochlerotatus atlanticus*, *O. taeniorhynchus*, *Psorophora ferox* and *Culiseta melanura*. Environmental conditions recorded during the studies were within acceptable limits.

I. A. **MRID 469774-24:**

Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine.

Efficacy was expressed as the average Complete Protection Time (CPT) from time of application of the repellent to First Confirmed Bite (FCB). A bite is defined as a mosquito penetrating the skin with its proboscis and taking sufficient blood to cause swelling of its abdomen. A first bite is confirmed by a second one occurring within 30 minutes apart (pg. 17 of 104). The criteria for breakdown was 2 sequential mosquito bites 30 minutes apart from each other (pg. 8 of 104). Biting pressure was determined from landings, and landings were monitored intermittently (5 minutes every half an hour) by control subjects during the test. The whole body count on the control subject ranged from 11 to 41 landings per minute during exposure period (Appendix III). According to the study protocol, whole body counts will be taken at initiation of the study and then hourly (pg. 17 of 104). The exposed 250 sq. cm skin of the 2 control subjects received from 5 to 43 landings per five minute exposure periods throughout the test (Appendix III and IV). The test lasted 8 hours (pg. 8 of 104).

The lotion formulation containing 15 % w/w active ingredient was applied at a dose of 0.63 g per 250 sq. cm of subject's skin. The lotion formulation containing half the concentration of the active ingredient (7 % w/w) was applied at a dose of 0.64 g per 250 sq. cm of subject's skin. Liquid formulations at 15 % w/w and 7 % w/w were both applied at the same dose of 0.43 ml per 250 sq. cm of skin surface area to ensure full

coverage (pg. 7 of 104). On page 16 of 104, it is stated that the amount of formulations applied were 62 g and 0.4 g / 250 sq. cm of skin surface for lotions and liquids, respectively.

These formulations were tested individually and simultaneously on separate arms of the same test subjects. Subjects were treated in pairs (pg. 17 of 104). Treatment formulations containing the highest concentration of active ingredient (15 % w/w) were replicated on 10 test subjects. Formulations containing half that concentration of active ingredient (7 % w/w) were also tested individually and simultaneously on 5 additional subjects (pg. 8 of 104).

The Lotion, containing 15% w/w of *hydrogenated catmint oil*, provided an average of 8 hours of protection with no measurement of mean deviation. The Liquid formulation, containing the same concentration of active ingredient (15% w/w), provided 7.48 (± 0.26) hours of protection. The lotion and liquid formulations containing 7 % of the active ingredient provided approximately 7.33 (± 0.33) hours of protection, and 4 (± 1.58) hours of protection, respectively (pg. 9 of 104). The data was not statistically analyzed for comparison of treatment means.

I. B. MRID 469774-25:

Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida

Efficacy was expressed as the average Complete Protection Time (CPT) from time of application of the repellent to First Confirmed Bite (FCB). A bite is defined as a mosquito penetrating the skin with its proboscis and taking sufficient blood to cause swelling of its abdomen. A first bite is confirmed by a second one occurring within 30 minutes apart (pg. 17 of 104). The criteria for breakdown was 2 sequential mosquito bites 30 minutes apart from each other (pg. 8 of 104). Biting pressure was determined from landings, and landings were monitored intermittently (5 minutes every half an hour) by control subjects during the test. The whole body count on the control subject ranged from 7 to 49 landings per minute during exposure period (Appendix III). According to the study protocol, whole body counts will be taken at initiation of the study and then hourly (pg. 17 of 104). The exposed 250 sq. cm skin of the 2 control subjects received from 5 to 43 landings per five minute exposure periods throughout the test (Appendix III and IV). The test lasted 8 hours (pg. 8 of 104).

The Lotion formulation containing 15 % w/w active ingredient was applied at a dose of 0.63 g per 250 sq. cm of subject's skin. The lotion formulation containing half the concentration of the active ingredient (7% w/w) was applied at a dose of 0.64 g per 250 sq. cm of subject's skin. Liquid formulations at 15 % and 7 % w/w were both applied at the same dose of 0.43 ml per 250 sq. cm of skin surface area to ensure full coverage (pg. 7 of 104). On page 16 of 104, it is stated that the amount of formulations applied were 62 g and 0.4 g / 250 sq. cm of skin surface for lotions and liquids, respectively.

These formulations were tested individually and simultaneously on separate arms of the same test subjects. Subjects were treated in pairs (pg. 17 of 104). Treatment formulations containing the highest concentration of active ingredient (15% w/w) were replicated on 10 test subjects. Formulations containing half that concentration of active ingredient (7% w/w) were also tested individually and simultaneously on 5 additional subjects (pg. 8 of 104).

The Lotion, containing 15% w/w of *hydrogenated catmint oil*, provided an average of 6 (± 1.05) hours of protection. The Liquid formulation, containing the same concentration of active ingredient (15% w/w), provided 5.14 (± 0.22) hours of protection. The lotion and liquid formulations containing 7 % of the active ingredient provided approximately 6 (± 1.34) and 4 (± 0.42) hours of protection, respectively (pg. 9 of 104). The data was not statistically analyzed for comparison of treatment means.

II. STUDY DESIGN

II A. **MRID 469774-24:**

The study was conducted as described in the study protocol (G3130306001A044), except for 2 deviations: 1) the lotion formulations were not applied by weight as proposed on the test protocol. Due to the limited amount supplied by the sponsor, an applicator stick was inserted directly into the sample container and then, the sample container with the applicator were placed on scale to treat subjects rather than placing sufficient material in a weigh pan, including the applicator stick, and then placing the weigh pan on the scale (pages 7 and 27 of 104). A new applicator was used for each subject as described in the protocol. 2) Characterization of sample is not included in the final study report as specified in the protocol. ICR retains that information in their facility (pages 7 and 27 of 104).

The protocol proposed at least 2 test sites, in Maine and Florida. The sites selection was based on unobstructed space, mosquito species composition and landing rates in the range of 1 to 10 landings per minute on a 250 sq. cm of exposed skin. As stated on the study protocol, landing rates on test site selection will be monitored by support staff and/or the study Director, who will expose their untreated limb at likely sites through the area (pg. 15 of 104). The protocol proposes 12 subjects per test, 2 of which will be randomly chosen to serve as controls. Control subjects will expose 250 sq. cm of untreated skin intermittently for 5 minutes every half an hour throughout the course of the study. During the test, a whole body count of mosquitoes landing on one of the controls will be taken at initiation of the test, and then hourly during the course of the study. Test subjects will expose treated arms continuously for 8 hours or until First Confirmed Bite occurs (pg. 17 of 104).

As specified on the study protocol, subjects will prepare their arms for repellent treatments prior to arrival at the field site. Repellent treatments will be randomly applied to subjects at the vicinity of the test site. It is stated on page 16 of 104 of the study

protocol that the amount of repellent applied per subject per treatment will be 0.4 g. of liquid formulation, and 0.62 grams of the lotion formulation. The liquid formulation will be applied using a syringe. The lotion formulation will be applied by weight using a stick applicator. This procedure is described further on the same page: "The container with the lotion formulation will be placed on a scale including an applicator stick, and the scale will be tared. Each time the negative value of 0.62 g appears on the scale, the target weight would have been applied using an applicator stick." (pg. 16 of 104).

Test subjects will be treated in pairs, each member of a pair will be treated with one formulation, and then the other formulation. CPT will be the lapse of time from application of the second repellent formulation to time of first confirmed bite (pg. 17 of 104). Mosquitoes landing on control subjects will be aspirated and held for subsequent identification (pg. 18 of 104).

Appropriate statistical analysis will be conducted. Efficacy data will be reported as mean hours and minutes of complete protection (pg.19 of 104).

This protocol was amended for additional testing of liquid and lotion formulations containing 7% active ingredient. Five additional subjects were used for evaluating these 2 formulations simultaneously. Each subject will test both formulations, each of them on a separate arm (pg. 25 of 104).

II. STUDY DESIGN

II. B. MRID 469774-25:

The study was conducted as described in the study protocol (G3130306001A044), except for 2 deviations: 1) the lotion formulations were not applied by weight as proposed on the test protocol. Due to the limited amount supplied by the sponsor, an applicator stick was inserted directly into the sample container and then, the sample container with the applicator were placed on scale to treat subjects rather than placing sufficient material in a weigh pan, including the applicator stick, and then placing the weigh pan on the scale (pages 7 and 27 of 104). A new applicator was used for each subject as described in the protocol. 2) Characterization of sample is not included in the final study report as specified in the protocol. ICR retains that information in their facility (pages 7 and 27 of 104).

The protocol proposed at least 2 test sites, in Maine and Florida. Sites selection was based on unobstructed space, mosquito species composition, and landing rates in the range of 1 to 10 landings per minute on a 250 sq. cm of exposed skin. As stated on the study protocol, landing rates on test site selection will be monitored by support staff and/or the study Director, who will expose their untreated limb at likely sites through the area (pg. 15 of 104). The protocol proposes 12 subjects per test, 2 of which will be randomly chosen to serve as controls. Control subjects will expose 250 sq. cm of untreated skin intermittently for 5 minutes every half an hour throughout the course of the

study. During the test, a whole body count of mosquitoes landing on one of the controls will be taken at initiation of the test, and then hourly during the course of the study. Test subjects will expose treated arms continuously for 8 hours or until First Confirmed Bite occurs (pg. 17 of 104).

As specified on the study protocol, subjects will prepare their arms for repellent treatments prior to arrival at the field site. Repellent treatments will be randomly applied to subjects at the vicinity of the test site. It is stated on page 16 of 104 of the study protocol that the amount of repellent applied per subject per treatment will be 0.4 g. of liquid formulation, and 0.62 grams of the lotion formulation. The liquid formulation will be applied using a syringe. The lotion formulation will be applied by weight using a stick applicator. This procedure is described further on the same page: "The container with the lotion formulation will be placed on a scale including an applicator stick, and the scale will be tared. Each time the negative value of 0.62 g appears on the scale, the target weight would have been applied using an applicator stick." (pg. 16 of 104).

Test subjects will be treated in pairs, each member of a pair will be treated with one formulation, and then the other formulation. CPT will be the lapse of time from application of the second repellent formulation to time of first confirmed bite (pg. 17 of 104). Mosquitoes landing on control subjects will be aspirated and held for subsequent identification (pg. 18 of 104).

Appropriate statistical analysis will be conducted. Efficacy data will be reported as mean hours and minutes of complete protection (pg.19 of 104).

This protocol was amended for additional testing of liquid and lotion formulations containing 7% active ingredient. Five additional subjects were used for evaluating these 2 formulations simultaneously. Each subject will test both formulations, each of them on a separate arm (pg. 25 of 104).

III. RESULTS AND CONCLUSIONS

III. A. MRID 469774-24:

The average number of landings on each control subjects were 14.6 and 17.1 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.4 landings, ranging from 11 to 41 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 8 hours with no deviations (n=10)
The mean CPT for the Liquid (15 % w/w) was 7.48 hours \pm 0.26 (n=10)
The mean CPT for the Lotion (7 % w/w) was 7.33 hours \pm 0.33 (n=5)
The mean CPT for the Lotion (7 % w/w) was 4.17 hours \pm 1.58 (n=5)

III. RESULTS AND CONCLUSIONS

III. B. **MRID 469774-25:**

The average number of landings on each control subjects were 12.1 and 20.4 per 5 minutes exposure, ranging from 5 to 43. The average count of landings on whole body suit was 20.9 landings, ranging from 7 to 49 landings. These whole body suit counts were taken hourly during 8 hours of intermittent exposure. (Appendix IV: statistics. Page 66 of 104). The duration of whole body suit's exposure periods are not specified in the report.

The mean CPT for the Lotion (15 % w/w) was 6.14 hours \pm 1.05 (n=10)

The mean CPT for the Liquid (15 % w/w) was 5.14 hours \pm 0.22 (n=10)

The mean CPT for the Lotion (7 % w/w) was 5.54 hours \pm 1.34 (n=5)

The mean CPT for the Lotion (7 % w/w) was 4.17 hours \pm 0.42 (n=5)

IV. REVIEWER COMMENTS OF MRID 469774-24 AND MRID 469774-25:

The repellency of 4 products, 2 lotion and 2 liquid formulations differing in their concentrations of the same active ingredient, were tested in 2 field sites, one site in Maine and another site in Florida. The report does not describe the different habitat characteristics at these 2 test sites. The report provides information on the species, and abundance of mosquito species found at each site. The environmental data shows that the weather was cloudy, humid and on the cold side in Maine (average temperature was high fifties and low sixties ° F); RH was between 80 and 94; and the wind speed was less than 1 MPH. The weather data from Florida shows that it was sunny for the first 4 hours of the test, and then it became cloudy with 100% cloud cover. Raw data collection sheet indicates that it started raining at the last 2 hours of the test. Apparently, this did not interfere with mosquito activity. The temperature was between 75 and 90 ° F, and RH was between 70 and 96. The wind speed was less than 1 MPH. These environmental conditions are within acceptable limits.

Neither Maine nor the Florida site was monitored for incidence of mosquito borne diseases prior to conducting the study. Site selection was based solely on unobstructed space, abundance and diversity of mosquito species, and mosquitoes' landing rate. All the mosquito species identified at these sites are potential vectors of WNV. While this is not a scientific issue, it has ethical implications.

The informed consent document states that subjects will be treated with less than 1 teaspoon full of formulation, which is the amount that would normally be applied to consumers. This study provides no indication of measuring a typical consumer dose to determine that the amount applied to subjects was the dose normally applied by consumers. The report shows some inconsistencies concerning the amount of test

material applied to subjects. On page 7 of 104, it is stated that the lotions will be applied at 0.63 and 0.64 g./ 250 sq. cm skin surface area for the 15% and 7% formulations, respectively. On pages 13 and 16 of 104, the application rate for the 15% lotion is 62g/ 250 sq. cm., and 0.4 g/ 250 sq. cm. for the liquid 15% formulation. However, the report also states that the liquid formulation was applied by volume using a syringe, and the volume will be determined based on the specific gravity of the material. The reported applications for the liquid formulations on page 7 of 104 are given in units of volume, ml., instead of grams as reported on pages 13 and 16.

The whole body count of mosquito landings was taken hourly for unspecified exposure periods throughout the study. The table on page 66 of 104 shows hourly counts and the mean of those landings: 20.9 average landings. It is stated on page 8 of 104, that these counts are per minute. Also on page 8 of 104, it is reported that the landing counts on untreated skin of test subjects are recorded as number of landings per 5 minutes exposure. The information regarding landings rate should be reported on the table.

The endpoint in this study was the First Confirmed Bite, with subjects being continuously exposed to mosquitoes in the field. Frequency of mosquito landings is a good indicator of repellent breakdown. Risk to subjects from continuous exposure to mosquitoes in the field can be minimized by changing the endpoint from bites to landings, and exposing subjects to mosquitoes intermittently for short periods of time.

According to the study protocol, two test substances will be tested simultaneously on separate arms of the same subject. EPA specifically discourages testing more than one product on the same subject, unless the researcher can verify that the proximity of the 2 formulations on the same subject won't compromise the results.

Statistical data analysis is not discussed in any detail. The experimental design could have been analyzed as a 2 X 2 factorial (factors are 2 types of formulation – lotion and liquid - by 2 concentrations of active ingredient), for mean comparison with possible interaction or treatment main effect.

Lastly, the study report only provides a brief summary of the results and conclusion. The report is based entirely on the study protocol as amended. The actual study should be reported as conducted consistently with a copy of the study protocol.

Linda Hollis/DC/USEPA/US
04/20/2007 08:57 AM

To Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
cc Leonard Cole/DC/USEPA/US@EPA, Raderrio
Wilkins/DC/USEPA/US@EPA, Shannon L Koerber
<Shannon.L.Koerber@usa.dupont.com>,
bcc
Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of
Nepeta cataria; PRIA Date

Dear Mr. McEntee: Your message below to Mr. Raderrio Wilkins suggests that you are unwilling to renegotiate the due date for the above products to our requested date of March 2008. Rather, you state that December 21, 2007 is the date acceptable to you. When we met in our offices in March 5th 2007, your packages were still incomplete. As a result of our meeting I forwarded to you the message immediately below: We are unable to accomodate your request of a due date of December 21, 2007 and will need to renegotiate to the said date of March 2008. If you are still unwilling to renegotiate to this date then we most likely not be able to complete our reviews by the current date.

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.
2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete its review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.
3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (751:P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)

Linda Hollis/DC/USEPA/US

04/05/2007 01:26 PM

To Thomas.C.McEntee@usa.dupont.com

cc andersen.janet@epa.gov, wilkins.raderrio@epa.gov,
cole.leonard@epa.gov, wilkins.raderrio@epa.gov,
fuentes.clara@epa.gov

bcc

Subject Catnip Oil Products - The Tech and 2 ep's - Request to
Renegotiate

Mr. McEntee: I am writing to you in response to your email to Mr. Raderrio Wilkins of my staff in which you agree to renegotiate the due date for your three pending products from Nov. 17, 2007 to December 21, 2007. The due date of December 21, 2007 is proposed by you based on the fact that you are in disagreement that BPPD will need to negotiate out 3 months from the original due date as communicated to you by me in our meeting of March 1, 2008. We are requesting 3 months of extended time because our records show that the 86-5 deficiencies in addition to deficiencies found during the BPPD preliminary screening and communicated to you in our meeting of March 1st and subsequent email from me to you on March 5th have taken that amount of time for completion. If you recall that during our meeting of March 1st, your submission packages were still deficient. During this meeting and in my follow up email to you where I again described the information necessary to make your packages complete, I stated that the proposed due date will be March 2008 and that there may be the chance that the Agency will complete its review prior to that due date. Therefore, our request is to renegotiate the due dates for the above products to March 31, 2008 and I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.

An additional new development that may potentially affect the due date is your most recent submission of documents per 1303 which are not 86-5 compliant. We will need to communicate those deficiencies to you (if they have not been already) and allow you the time to correct them. Time added to correct 86-5 deficiencies can have an impact on the PRIA due date.

I apologize if you do not fully understand our process however, it is imperative that we are afforded the time required for each phase of the pria review process so that we are better able to make our regulatory decisions by the dates provided.

I look forward to hearing from you so that we can move this forward.

P.S. As discussed with you in our March 1st meeting, please include or carbon copy me, Linda Hollis, in your communications to John Carley relative to information that you will be submitting.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)



Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

03/29/2007 12:29 PM

To Raderrio Wilkins/DC/USEPA/US@EPA

cc Leonard Cole/DC/USEPA/US@EPA, Linda Hollis/DC/USEPA/US@EPA, Shannon L Koerber
<Shannon.L.Koerber@usa.dupont.com>

bcc

Subject Re: EPA File Symbols 71654-ER, EG and EN; Refined Oil of Nepeta cataria; PRIA Date

Mr. Raderrio Wilkins,

This is to confirm that I have discussed the subject of negotiated PRIA decision date with our management. Because of the time it took to resolve the 86-5 defects, we are agreeable to a PRIA date of December 21, 2007 for 71654-EN and ER. The 71654-EG can be extended although I would expect EPA to reach the same decision as is reached for 71654-ER.

EPA file symbols 71654-EN and 71654-ER were submitted Nov. 1, 2007 and the PRIA fee paid on Nov. 11. Because the confidential appendices were incorrectly paginated per 86-5 there was a delay until mid-December.

You mentioned the front-end screen and a gap associated with the screen. I lack insight into this activity and I'm unable to understand the justification for requesting a three month extension (until March 2008).

Should there be issues with the studies that have been submitted for review, there could be a basis to request an extension in order to respond to the issues. Presently, with the studies in primary review, it is difficult to appreciate that BPPD will not be in a position to make a decision on these applications by December 2007.

As discussed in the March 1, 2007 meeting with Ms. Linda Hollis, Roger Gardner, Russell Jones and Leonard Cole, the goal is to be able to bring this product to market for the US 2008 summer season. Obtaining the registration in March gives insufficient lead time to address the practical aspects of commercial agreement, supply, state registrations, advertising, logistics and etc. While extending a 12 month process to 15 months is not a large percentage increase, it does have a critical effect on the commercial timing with significant consequences to our business interests. Therefore, I respectfully request that we work together to secure a December 2007 approval.

Thank you for your assistance with our applications for registration.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

03/05/2007 10:49
AM

To
Thomas C McEntee/AE/DuPont@DuPont
cc

wilkins.raderrio@epa.gov,
cole.leonard@epa.gov

Subject
Re: EPA File Symbols 71654-ER, EG

and EN; Refined Oil of Nepeta
cataria

Dear Mr. McEntee:

Per our meeting of March 1, 2007 we discussed several administrative deficiencies with regard to your products which are as follows: Please provide:

1. An updated data matrix for all of your products as referenced above. The updated data matrix should list the Tier 1 data requirements for Non target fate and effects and indicate how you intend to satisfy each data requirement. Should the data requirement fall under the category of not applicable, please so state. You may fax these forms to Leonard Cole at 703-305-0118. The forms are needed immediately but will not prevent your data from entering into the first phases of scientific review.
2. As discussed, the Agency will need to renegotiate the due date for these products. The current due date is Nov. 17, 2007. We will need to renegotiate out 3 months due to time lost to correct 86-5 deficiencies. The proposed due date will be March 2008. Of course, there may be the chance that the Agency will complete's it's review prior to that due date. As indicated in our meeting, I will need for you to confirm, via email, that the proposed new due date is acceptable in order that we may commence with the paper work for renegotiation.
3. The risk manager who will be assigned to your submissions is Mr. Raderrio Wilkins. As discussed, I encourage you to communicate with Mr. Wilkins with regard to the status of your applications however, please refrain from contacting him until the end of next week to allow him the opportunity to process the application materials as he will not be in receipt of these materials until the end of this week.

I look forward to hearing from you with regard to the proposed due date and receiving your administrative materials.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
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Visit <http://www.epa.gov/pesticides>

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

02/28/2007 11:01 AM

Leonard Cole/DC/USEPA/US@EPA,
Linda Hollis/DC/USEPA/US@EPA

To

cc

Subject
Confirm Meeting - Thursday March
1, 2007 10:30 am EPA File
Symbols 71654-EG and RE; Refined
Oil of Nepeta cataria lotion

Confirm Meeting - Thursday March 1, 2007 10:30 am- EPA Potomac Yard
Refined Oil of Nepeta cataria
EPA File Symbols 71654-EG (7%Lotion) [23]
ER(15%Lotion) [21]
EN (Technical & manufacturing use) [20]

Mr. Leonard Cole and Ms. Linda Hollis,

This is to confirm the subject meeting. Notes from previous meetings are attached for your reference.

Please let me know if there will be anyone else in attendance besides yourselves.

(See attached file: 20060405 Meeting Notes.doc) (See attached file: 20051207 Meeting Notes.doc) (See attached file: March 17 2005 Meeting Intent Talking points.doc) (See attached file: EPA DuPont Dec 14 2004.doc)

Tom McEntee
302 695 6856
978 335 8055 CELL

Cole.Leonard@epam
ail.epa.gov

To

02/23/2007 09:08

Thomas C McEntee/AE/DuPont@DuPont

AM

cc

David L

Hallahan/AE/DuPont@DuPont,

Koerber/AE/DuPont@DuPont,

Shannon L

Yesenia M Pelaez/AE/DuPont@DuPont

Subject

Re: EPA File Symbols 71654-EG and
RE; Refined Oil of Nepeta cataria
lotion; Ref: telephone Feb 21

2007

Thanks Tom. This is a non-issue. I apologize for creating a stir. After carefully reviewing things and adding thought, I realized that this is a non-food use, and you have provided CAS Reg. Numbers for the inerts. We may have some other minor issues. I'll be in touch with you very soon. I appreciate your patience and understanding.

Leonard Cole

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

02/22/2007 02:06
PM

Leonard Cole/DC/USEPA/US@EPA

To

cc

Shannon L Koerber
<Shannon.L.Koerber@usa.dupont.com
>, Yesenia M Pelaez
<Yesenia.M.Pelaez@usa.dupont.com>
, David L Hallahan
<David.L.Hallahan@USA.dupont.com>

Subject

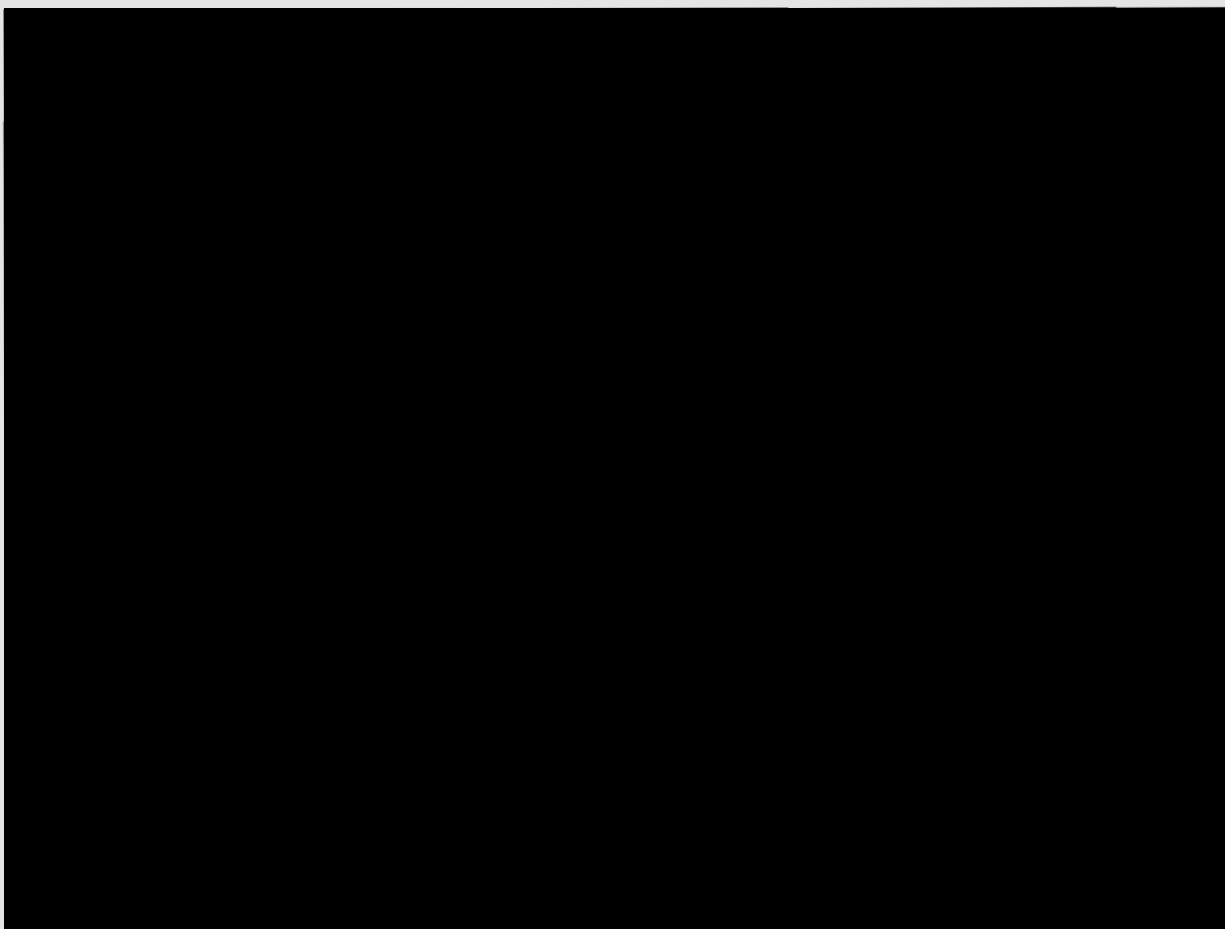
EPA File Symbols 71654-EG and RE;
Refined Oil of Nepeta cataria
lotion; Ref: telephone Feb 21
2007

Mr. Leonard Cole

Thank you for your telephone call regarding the subject product and details regarding four of the inerts in the formulation. Please refer to the bookmarked attachments for further documentation of the four ingredients discussed yesterday.

(See attached file: [REDACTED].pdf)

(See attached file: 20070222 Inerts Complete list.pdf)



Sincerely and thanks for your attention to our applications.

Tom McEntee
302 695 6856
978 335 8066 CELL

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Intent Talking points.doc)(See attached file: EPA DuPont Dec 14
2004.doc)(See attached file: [REDACTED]
[REDACTED].pdf)(See attached file: 20070222 Inerts
Complete list.pdf)(See attached file: [REDACTED]
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(See attached file: 20060405 Meeting Notes.doc)(See attached file: 20051207
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points.doc)(See attached file: EPA DuPont Dec 14 2004.doc)(See attached
file: [REDACTED]
[REDACTED].pdf)(See attached file: 20070222 Inerts Complete list.pdf)(See
attached file: [REDACTED].pdf)(See
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DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

TRANSMITTAL FAX
(703) 305 0118

March 15, 2007

Mr. Leonard Coles
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent
"Refined Oil of *Nepeta cataria* 7% Lotion"; EPA File Symbol : 71654-EG

Please find the attached supplemental Data Matrix, which has been completed for the subject product in reference to the Tier 1 Non-Target organism testing requirements.

Should you have any questions please feel free to call.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas C. McEntee", written in a cursive style.

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 696 6856
(978) 887 6200 Alternate

human .

The data were referred to be those of the 15% formulation but were not submitted with this package.

The subject application (PRIA Category Code **B 60**) has a decision due date of [**enter due date**]. At this time, the application is considered incomplete until you address all of the deficiencies identified in this letter. Per 40 CFR 152.105, your application will be administratively withdrawn without further notice to you if you do not submit the missing information within 75 days from the date of this letter. However, submission of the above information by or on the 75 day due date (**enter calculated time**) will not allow BPPD enough time to process, conduct review and make a regulatory decision by the PRIA due date of [**enter due date**]. Therefore, BPPD requires that all deficiencies as stated above be addressed and resubmitted to the Agency within [**enter timeframe**] days from the date of this letter. Please submit the above materials immediately to Linda Hollis by fax (703) 305-0118 or hollis.linda@epa.gov .

Sincerely,

Janet L. Andersen, Ph.D.
Biopesticides and Pollution Prevention Division
7511C

Fee for Service

{802293}~

This package includes the following

- New Registration
- Amendment

Studies? Fee Waiver?
volpay % Reduction: ____

for Division

- AD
- BPPD
- RD

Risk Mgr.

9/1? N
~~32~~

Receipt No.

S-

802293

EPA File Symbol/Reg. No.

71654-EG

Pin-Punch Date:

12/8/2006

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

~~B~~ DIDN'T

Granted:

B 60

Amount Due: \$ 15,750

Parent/Child Decisions:

Reviewer: S. Ruff

Date: 12/13/06

Remarks:

BPPD SCREEN PACKAGE

BPPD FRONT END: BPB/MPB: ^{Ant.} Team Leader: 2. Gk

Pria Code/Action Code: B60 Team/RAL: _____

Product Name: ~~71654-EG~~ Refined Oil of Nepeta cataria

EPA ID No.: 71654-EG

Active Ingredient(s): Nepeta cataria oils

_____ Food _____ New Submission

☒ Non Food _____ Resubmission

Date In BPPD: 1/3/07

Date To Screen: 1/19/07

Date Expected From Screen: (10 days from date in): 1/30/07 WA# 06-67

Nasrin Begum: ~~Henry Adams~~ Hours 3-5 Return to BPPD: 1/26/07

Received Date from Contactor: 1/26/07 [Signature]

SCREEN PACKAGE NOTES:

Pre- Reg Meetings attached? _____ Yes X No

Submission complies with all applicable areas of checklists? Indicate in detail on checklists forms when returned.

Additional Comments per Team Leader or Screener:

SCREEN STATUS

Administrative: _____ Pass _____ Fail

Scientific: _____ Pass _____ Fail



DuPont Chemical Solutions Enterprise

December 5, 2006

Dr. Russell Jones
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent

"Refined Oil of *Nepeta cataria* 7% Lotion"; EPA File Symbol : 71654- 


This letter and its attachments comprise DuPont's application for registration of a new insect repellent end-use product, **Refined Oil of *Nepeta cataria* 7% Lotion**. EPA File Symbol 71654-ER; **Refined Oil of *Nepeta cataria* 15% Lotion** dated October 18, 2006 is substantially similar, differing only in concentration of the active and several non-active ingredients. The 15% active product reflected Category IV (40CFR156.62) for all five studies that were conducted and should qualify for waiver/non-applicability from the requirement for inhalation toxicity testing. The applicant requests that EPA bridge the studies from the 15% formula to the 7% product.

These two end-use applications and the technical/manufacturing-use concentrate are based on the technology discussed with you and your staff on December 14, 2004, March 17, 2005 and February 27, 2006. During those discussions the active ingredient was referred to as **HYDROGENATED CATMNT OIL**. The product name and active ingredient name have been changed to facilitate global recognition and acceptance.

Besides the **Refined Oil of *Nepeta cataria* 15% and 7% Lotions**, two substantially similar end-use formulations which contain solutions of **Refined Oil of *Nepeta cataria***, will be submitted, most likely in the second quarter of 2007.

Thank you for your assistance during the pre-registration phase of this program. Should there be any questions, please feel free to call.

Sincerely,


Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number

E. I. duPont de Nemours and Company; P. O. Box 80402 Wilmington, DE 19880 (302) 695 6856

EPA Registration Number/File Symbol

71654-

Active Ingredient(s) and/or representative test compound(s)

Refined Oil of Nepeta cataria

Date

December 5, 2006

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)

Insect Repellent Formulas for Human Use - End-Use Product

Product Name

Refined Oil of Nepeta cataria 7% lotion

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Thomas C. McEntee

Date

Dec. 5, 2006

Typed or Printed Name and Title

Thomas C. McEntee; Product Registration Manager



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 71654- EG	2. EPA Product Manager PM# 302 91	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Refined Oil of Nepeta cataria 7% Lotion	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	
5. Name and Address of Applicant (Include ZIP Code) E.I. du Pont de Nemours and Company Dupont Chemical Solutions Enterprise, P. O. Box 80402 Experimental Station (ESL402/3224C) Wilmington, DE 19880-0402 <input type="checkbox"/> Check if this is a new address		

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for registration of new biochemical pesticide end-use formula. This application is substantially similar to EPA File Symbol 71654-ER, Refined Oil of Nepeta cataria 15% Lotion. The formulation differs only in the level of active ingredient and an adjustment of the non-actives to make-up for the lower level of active ingredient.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input checked="" type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Thomas C. McEntee	Title Product Registration Manager	Telephone No. (Include Area Code) 302 695 6856
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		8. Date Application Received (Stamped) 183
2. Signature 	3. Title Product Registration Manager	
4. Typed Name Thomas C. McEntee	5. Date December 5, 2006	

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E. I. DUPONT DE NEMOURS & COMP
DuPont Payment Services
P. O. Box 80040
Wilmington, DE 19880-0040

10/10/06

US GOVT
US EPA WASHINGTON FINANCE CTR
PESTICIDE REGISTRATION SVC FEED
PO BOX 360277
PITTSBURGH, PA 15251-6277

DOCUMENT NO.	INVOICE NO.	DATE	GROSS	DISCOUNT	NET
1500701510	EPAAPEX838HC0A	09/14/06	4,200.00	0.00	4,200.00
TOTALS			\$4,200.00	0.00	\$4,200.00

Questions regarding faster deposits through Electronic Funds Transfers, Please e-mail
DPS.Wilm@USA.Dupont.com; For payment questions, please e-mail AP2@USA.DuPont.com

Attachment
Check # 3000068102

THE FACE OF THIS CHECK IS PRINTED BLUE - THE BACK CONTAINS A SIMULATED WATERMARK



E. I. DUPONT DE NEMOURS & COMPANY
DuPont Payment Services
P. O. Box 80040
Wilmington, DE 19880-0040

62-20
311

No. 3000068102

PAY TO
THE ORDER OF

US GOVT
US EPA WASHINGTON FINANCE CTR
PESTICIDE REGISTRATION SVC FEED
PO BOX 360277
PITTSBURGH, PA 15251-6277

10/10/06

*****\$4,200.00

Four thousand two hundred and 00/100 Dollars

CITIBANK DELAWARE
A SUBSIDIARY OF CITICORP
ONE PENN'S WAY
NEW CASTLE, DE 19720

⑈ 3000068102 ⑈

TRANSMITTAL DOCUMENT

Attention:

Document Processing Desk (REGFEE)
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

NAME AND ADDRESS OF SUBMITTER

E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL 402/3442A)
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Application for New Pesticide Registration End-Use Product

Refined oil of *Nepeta cataria* 7% Lotion; EPA File Symbol 71654-

Transmittal Date: **December 5, 2006**

Transmittal Material:

Volume 1 Administrative Materials

- Cover Letter	1 page
- Application for Pesticide Registration (EPA Form 8570-1)	1 page
- Transmittal Document	1 pages
- CSF (EPA Form 8570-4), December 5, 2006	2 pages
- Data Matrix EPA form (8570-35)	2 pages
- Certification Data Citation (8570-34)	1 page
- Five copies of labeling	4 pages
- Copy Check No. 3000068102	1 check



Refined Oil of *Nepeta cataria* 7 % Lotion

Insect Repellent Lotion

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)
- Long lasting effective protection against mosquitoes and other biting insects (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Uncompromised Performance (OPT)
- (Natural) Complete Outdoor protection (OPT)
- (Safe) Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Dependable Protection from Nature (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains a botanically-derived insect repellent (OPT)
- Contains (a) plant-based repellent (OPT)



- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)
- Botanical(!) (OPT)
- New Plant based ingredient with uncompromised efficacy (repellency) (OPT)
- Plant based ingredient (– does not settle for less efficacy) (OPT)
- Contains plant extracts (OPT)
- (uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)
- (Confidence in) Natural Protection (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Natural) (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- How Nature protects (from biting insects) (OPT)
- (Smart) protection with confidence from nature (OPT)
- For playing and relaxing outdoors (OPT)
- Dermatologist Tested (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- No need to wash off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- The safe choice (OPT)
- (Smart) (and) (safe) choice (OPT)
- Readily washed off (OPT)
- New! (OPT)



ACTIVE INGREDIENT:

Refined Oil of <i>Nepeta cataria</i>	7.0%
Other Ingredients	93.0%
Total	100.0%

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:

E.I. du Pont de Nemours and Company

PO Box 80402

Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Avoid Contact with Eyes.

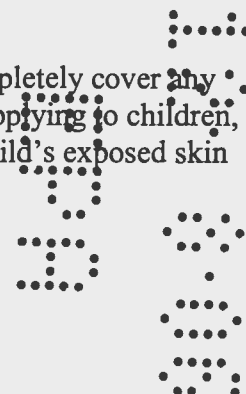
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves.

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.



FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If a reaction to this product is suspected:

- Discontinue use.
- Take off contaminated clothing.
- Wash skin thoroughly with plenty of water .
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

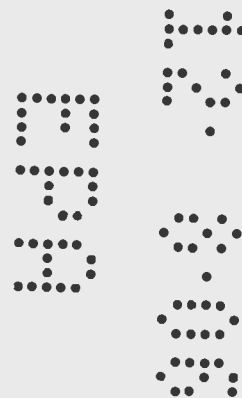
Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain



Refined Oil of *Nepeta cataria*
7 % Lotion

Insect Repellent Lotion

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)
- Long lasting effective protection against mosquitoes and other biting insects (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Uncompromised Performance (OPT)
- (Natural) Complete Outdoor protection (OPT)
- (Safe) Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Dependable Protection from Nature (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains a botanically-derived insect repellent (OPT)
- Contains (a) plant-based repellent (OPT)



- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)
- Botanical(!) (OPT)
- New Plant based ingredient with uncompromised efficacy (repellency) (OPT)
- Plant based ingredient (– does not settle for less efficacy) (OPT)
- Contains plant extracts (OPT)
- (uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)
- (Confidence in) Natural Protection (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Natural) (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- How Nature protects (from biting insects) (OPT)
- (Smart) protection with confidence from nature (OPT)
- For playing and relaxing outdoors (OPT)
- Dermatologist Tested (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- No need to wash off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- The safe choice (OPT)
- (Smart) (and) (safe) choice (OPT)
- Readily washed off (OPT)
- New! (OPT)



ACTIVE INGREDIENT:

Refined Oil of <i>Nepeta cataria</i>	7.0%
Other Ingredients	93.0%
Total	100.0%

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Avoid Contact with Eyes.

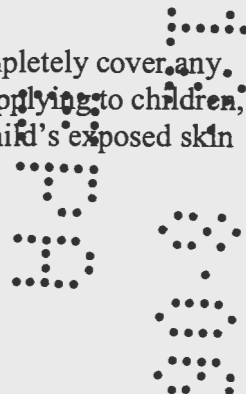
DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves.

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.



FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If a reaction to this product is suspected:

- Discontinue use.
- Take off contaminated clothing.
- Wash skin thoroughly with plenty of water .
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

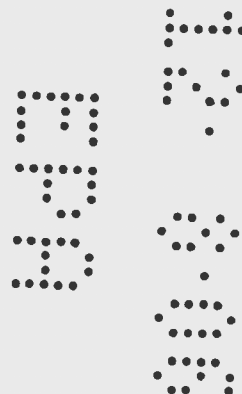
For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Storage:

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain



ACTIVE INGREDIENT:

Refined Oil of <i>Nepeta cataria</i>	7.0%
Other Ingredients	93.0%
Total	100.0%

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

~~Avoid Contact with Eyes.~~

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves.

Dispense a small amount of lotion directly onto skin. Spread uniformly to completely cover any exposed skin surface. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

After returning indoors, wash treated skin with soap and water or bath. Also wash treated clothing before wearing it again.
move to bottom

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If a reaction to this product is suspected:

- Discontinue use.
- Take off contaminated clothing.
- Wash skin thoroughly with plenty of water .
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

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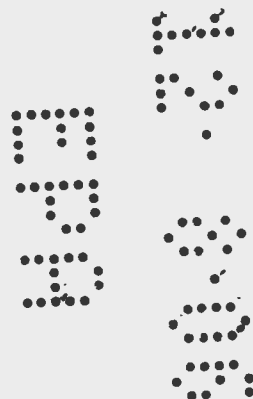
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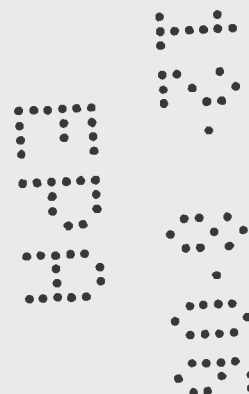
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To Hand
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Refined Oil of *Nepeta cataria* 7 % Lotion

Insect Repellent Lotion

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (~~uncompromised~~) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- ~~Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)~~
- ~~Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)~~
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- ~~As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)~~
- ~~Long lasting effective protection against mosquitoes and other biting insects (OPT)~~
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- ~~Uncompromised Performance (OPT)~~
- ~~(Natural)~~ Complete Outdoor protection (OPT)
- ~~(Safe)~~ Guards the whole family (~~safety~~) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- ~~Dependable Protection from Nature (OPT)~~
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT)
- ~~Safety outdoors for play and on the go (OPT)~~
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- ~~Contains a botanically-derived insect repellent (OPT)~~
- Contains (a) plant-based repellent (OPT)



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- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)
- ~~Botanical(!) (OPT)~~
- ~~New Plant based ingredient with uncompromised efficacy (repellency) (OPT)~~
- Plant based ingredient (– does not settle for less efficacy) (OPT)
- Contains plant extracts (OPT)
- ~~(uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)~~
- ~~(Confidence in) Natural Protection (OPT)~~
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- ~~(Natural)~~ (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- ~~How Nature protects (from biting insects) (OPT)~~
- ~~(Smart) protection with confidence from nature (OPT)~~
- For playing and relaxing outdoors (OPT)
- ~~Dermatologist Tested (OPT)~~
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- ~~No need to wash off (OPT)~~
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- ~~No residue on skin (OPT)~~
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- ~~The safe choice (OPT)~~
- ~~(Smart) (and) (safe) choice (OPT)~~
- Readily washed off (OPT)
- ~~New! (OPT)~~



